HUMAN SUBJECT RESEARCH POLICY

Applies To :

This document applies to all GTG Operations and Supported Research.

Introduction and Background or Purpose :

GTG supported Human Subject Research involves the evaluation, via Trial/Study, of an Investigational Product. Any use of human subjects in research requires careful attention to respecting and protecting the subject's rights and interests.

The following policy protects the rights, safety and welfare of human subjects who participate in GTG Supported Research.

Requirements or Expectations :

Overall responsibility for ensuring compliance with this document is assigned to GTG Sustainability & Product Stewardship organization.

All GTG Supported Research involving human subjects must be conducted in accordance with all applicable national, regional and local ethical and legal rules and regulations, and must be conducted in accordance with three commonly recognized principles, as described in the Belmont Report.

These are:

- **Respect for Persons** - research should be conducted on humans only with their knowledge and consent;
- **Beneficence** - risks to subjects have been minimized and are reasonable relative to the benefits and importance of knowledge gained;
- **Justice** - selection of subjects is equitable and the burdens and benefits of participating in research are fairly distributed.

GTG investigators and/or sponsors must ensure that Human Subject Research requiring review by an Institutional Review Board (IRB) receives the appropriate review in advance from the GTG IRB or other suitable ethical review committee. Excluded from this Policy are studies conducted on GTG materials by entities outside of GTG without GTG involvement or knowledge.

Additional Elements :

Definitions

Human Subject Research - Any research activity (systematic investigation designed to develop or contribute to general knowledge) via Trial/Study that obtains data through intervention or interaction with an individual, or obtains information by which an individual could be identified, for purposes other than the sole purpose of benefiting the subject as an individual.

Trial/Study - Any investigation in human subjects intended to discover or verify the effects of an Investigational Product(s), and/or to identify any reactions to an Investigational Product(s), and/or to study absorption, distribution, metabolism, and excretion of an Investigational Product(s) with the object of ascertaining its safety and/or efficacy.

Investigational Product - Any chemical substance, mixture, article, material or device (including drugs, placebo, therapy, and comparator) being tested or used as a reference in a Trial/Study. This includes marketed products and any products used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

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- **Supported Research** - Any research where GTG is the sponsor; or provides financial support or product to a 3rd party for the purposes of Human Subject Research. This research could be conducted on GTG premises, or at any other institution such as a hospital, dental office, private clinic, nursing home, university, research center, or contract laboratory.

- **Institutional Review Board (IRB)** - An independent ethics committee constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure protection of the rights, safety, and well-being of human subjects involved in Trials/Studies

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