

Council on Research Ethics (CORE)

CHARTER

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Version 1.0 Adopted January 15, 2004

1.0 Statement of Authority Establishing Council on Research Ethics and Jurisdiction

The Senior Vice President Global Risk Management and Quality Assurance for Quintiles Transnational Corp. (hereinafter referred to as Quintiles) authorized the formation and continuation of a research ethics council, called the Council on Research Ethics (CORE or Council), to monitor implementation of Quintiles' current version of Corporate Policy No. 003, Compliance and Quality (reproduced herein in Section 1.1) and standard practices and procedures designed to ensure ethics in research. This Council is affiliated with the Council on Data Protection (CODP) and shares some membership and advisors as appropriate.

The Senior Vice President, Global Risk Management and Quality Assurance designated the scope of the Council's jurisdiction to encompass all business initiatives and employees at Quintiles Transnational Corp., Quintiles' subsidiaries, affiliates, lines of business and other related entities.

1.1 Corporate Policy

Corporate Policy No.:	QTRN 003	Revision No:	2
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Title:	Compliance and Quality
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Approval:	Dennis Gillings, Ph.D. Chairman and Chief Executive Officer	Date:	January 1, 2001
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Policy Caretaker(s)	Vice President, Worldwide Quality Assurance
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Text:

It is the policy of Quintiles Transnational that Quintiles' business is carried out in conformance with all applicable ethical and legal standards. Accomplishing this goal requires, at a minimum, compliance with all applicable laws and regulations. Mindful that its services are performed in the pharmaceutical and health care industries, Quintiles will be particularly attentive to applicable ethical and regulatory standards. In fidelity to customers, Quintiles will honor its contractual commitments. Company policies and procedures must be followed to enable us to meet these requirements.

It is also the policy of Quintiles Transnational to provide Quintiles' customers worldwide with high-quality products and services. Quality includes delivering products of technical excellence and services that meet or exceed customer expectations. To meet this goal, each Business Group shall develop and

implement processes and programs which: (1) ensure the quality of the products and services it provides; (2) promote quality awareness; (3) provide appropriate staffing to deliver high-quality products and services; and (4) routinely monitor these quality programs.

Each Business Head is responsible for implementing this policy within their Business Group. Each Business Group must develop written procedures implementing this policy, following standards developed by or at the direction of the Quintiles Transnational Quality Assurance Department. Each employee is required to comply with this policy.

There will be periodic compliance and/or quality reviews within each Business Group performed by or on behalf of the Quintiles Transnational Quality Assurance Department. The Quality Committee of the Quintiles Transnational Board of Directors will receive reports on a periodic basis from the Quintiles Transnational Quality Assurance Department regarding reviews performed pursuant to this policy.

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1.2 Statement of Purpose

Quintiles, through the Council on Research Ethics (CORE), seeks to provide guidance on the implementation of Quintiles Corporate Policy No. 003, Compliance and Quality (reproduced herein in Section 1.1), and standard practices and procedures designed to address research ethics. Given the global nature of the corporation, Quintiles recognizes the ever-increasing need to consider ethical issues within Quintiles related to research. In addition, Quintiles is aware that various international regulatory authorities have issued or are issuing laws, regulations and directives which sometimes govern and other times serve as guidelines for issues related to research ethics.

The objective behind creating the CORE at Quintiles is to have one central, global organization which will monitor the evolving laws and regulations affecting research, taking into consideration the varied phases of research and the numerous regions within which Quintiles is involved in research activities. Practices implemented to this end are pursued for ethical considerations in research, including fostering and advancing the ethical and professional conduct of research with human participants.

Should Quintiles as a contract research organization seek accreditation for the protection of human subjects, a Task Force of a small number of CORE members will manage the application process and related activities going forward.

The issues arising in the area of research ethics within Quintiles are wide-ranging. Section 1.6 outlines some issues that may be considered by the Council.

1.3 Organizational Structure of CORE

- A. Criteria in General.** The CORE shall be comprised of at least 12 members, including the Chair and Vice-Chair. The members of the Council shall be broadly representative of the different areas, both geographically and topically, within which Quintiles is involved in various types of research. One member of this Council should be unaffiliated with Quintiles Transnational Corp., Quintiles' subsidiaries, affiliates, and related entities. The Council members should have backgrounds and appropriate professional competency necessary to review the various research policies, standard procedures and research protocols under consideration. It is desirable that Council members possess knowledge or expertise in various areas, which may include medical, regulatory, legal, quality assurance, clinical trial operations, product ownership, marketing, e-commerce, and nonregistrational research. Note that only **General Members** of the Council have voting rights.

- B. The CORE Chair** will be appointed by the Senior Vice President of Worldwide Quality Assurance. The Chair will serve until he or she appoints a new Chair or the Chair resigns.

The responsibilities of the Chair include:

- 1) serving as person responsible for monitoring the development and implementation of Quintiles' policies and procedures for ethics in research, making determinations, pertaining to research ethics matters, after consultation with Council members and advisors as appropriate;
- 2) directing the selection process for Vice-Chair and general members, advisors, and consultants of CORE;
- 3) convening CORE meetings and developing the agenda;
- 4) receive complaints related to research ethics and coordinate response / recommendations through CORE or Sub-panel of CORE;
- 5) determining the format / procedural order of meetings;
- 6) selecting and supervising the Information Coordinator and Recording Secretary;
- 7) supervising maintenance of records as specified in Section 1.5;
- 8) selecting Council members and advisors to comprise Task Forces as deemed appropriate by the Chair;
- 9) selecting Council members, advisors, and consultants to the Council to comprise Sub-panels for expedited review of critical ethical issues requiring immediate consideration;
- 10) proposing training programs for employees at Quintiles as specified;
- 11) facilitating the dissemination of standards for research ethics adopted for all employees and affiliates of Quintiles;
- 12) directing discussions of the CORE on research ethics matters;
- 13) determining whether expedited review of a particular research ethics matter is warranted, and, if so, perform the expedited review and recommendations or appoint one or more members for an expedited review;
- 14) signing, or designating a CORE member to sign, the documentation of review and recommendations by the Council of the research ethics matter under consideration;
- 15) disclosing, prior to voting on an issue review or discussion, all possible personal or financial conflicts of interest to the Council;
- 16) excusing himself or herself from participation in any research ethics issue review or discussion in which he or she has substantive conflict of interest.

- C. The CORE Vice Chair** will be appointed by the CORE Chair. The Vice Chair will serve a continuous term limited by his or her resignation or replacement according to the discretion of the CORE Chair. The responsibilities of the Vice Chair include

- 1) serving as Chair and fulfilling the Chair's responsibilities should the Chair be absent;

- 2) assisting the Chair with the selection process for general members;
- 3) assisting the Chair with the selection of Sub-panels for expedited review of critical issues requiring immediate consideration;
- 4) assisting the Chair regarding the receipt of complaints related to research ethics and coordinating response / recommendations through CORE or Sub-panel of CORE;
- 5) assisting the Chair in monitoring the dissemination and implementation of research ethics policies and procedures established by the CORE to all employees and affiliates of Quintiles;
- 6) disclosing, prior to review of a research issue, all possible personal or financial conflicts of interest to the Council;
- 7) informing the Chair of problems of which he or she becomes aware; and
- 8) assisting the Chair with the Chair's general duties.

D. The Chair or Vice Chair, in consultation with the Chair, shall appoint **General Members** of the CORE, who will represent various operations, groups, and geographic regions. Members will serve a continuous term limited by his or her resignation *upon thirty days' written notice*, or by removal or replacement, without notice, at the discretion of the CORE Chair.

The responsibilities of all members, including the Chair and Vice-Chair, include:

- 1) attending CORE meetings in person, teleconference, or videoconference and entering into discussion concerning issues surrounding subjects of review;
- 2) reviewing research ethics matters and evaluating these in terms of the criteria for approval as specified in Section 1.6;
- 3) making recommendations concerning policies and procedures for research ethics;
- 4) voting on recommendations regarding particular research issues;
- 5) excusing themselves from participation in any ethics issue review or discussion in which a member has a substantive conflict of interest;
- 6) disclosing all possible personal conflicts of interest to the Council; and
- 7) informing the Chair or Vice Chair of concerns related to research ethics.

E. Information Coordinator will be selected by the CORE Chair.

The responsibilities of the Information Coordinator include coordinating information exchange among Council members and advisors through various means, including emails, the CORE Intranet site, the QuickPlace CORE, and interoffice mail. This position has no formal term of office or voting rights.

The Chair at his or her discretion may remove the Information Coordinator from this position without notice.

F. The Recording Secretary will be selected by the CORE Chair.

This position has no formal term of office or voting rights. The same person may serve as both the Information Coordinator and Recording Secretary.

The responsibilities of the Recording Secretary include:

- 1) maintaining the records of minutes, copies of materials reviewed, a list of all CORE members, all CORE written procedures, and general communication files under the direction of the Chair;
- 2) providing notice and materials for meetings to members, and coordinating logistical details of meetings;
- 3) attending all meetings or finding a qualified substitute to attend in his or her place;
- 4) taking minutes of and recording CORE proceedings and distributing these minutes within the week following each meeting by email attachment and / or posting on the CORE QuickPlace;
- 5) erasing tapes of meetings after approval of the minutes; and
- 6) locating and forwarding materials to Council members upon request.

G. Consultants, Advisors, Liaisons, Outside Representative(s), including without limitation, medical, legal, regulatory, quality assurance, marketing, ethical, clergy, and public relations advisors, may be called upon to attend meetings in person, teleconference or videoconference and participate in discussions as requested by the Chair, Vice-Chair or general members of the Council (upon approval from the Chair). In particular, the Senior Director of the Business Ethics Office and Ethics HelpLine will engage CORE regarding any research ethical issues brought to the Senior Director's attention through the Office or Hotline. These CORE participants are not **GENERAL MEMBERS** and do not have voting rights.

1.4 Meetings

A. General Meetings

- 1)The Chair and Vice-Chair, under the direction of the Chair, have authority to convene general meetings.
- 2)General meetings will be held quarterly or more often as needed. Members should be notified one week in advance of upcoming general meetings, but must be given at least seventy-two hours notice of a scheduled meeting. If exigent circumstances so require, the Chair or Vice-Chair may call a meeting giving less notice, provided a reasonable good faith effort is made to contact all members of the Council. The notification period for sub-panel discussions may be shorter.

In order for the Council to vote on any issue in general meetings, a majority of members should be present, in person or by remote (such as teleconference or videoconference) and a majority of those voting is needed to support a recommendation. If there is no quorum, the Council can choose to table the issue for the next scheduled meeting.

- 3)The format / procedural order of meetings will be determined by the Chair or Vice-Chair, if the Chair so delegates.

B. Voting at General Meetings

- 1)No CORE member with a substantive conflict of interest may vote or participate in discussion on an issue unless requested to provide information by the Council.
- 2)Possible CORE actions taken by vote and documented in writing include:

Recommendation	Action taken if a majority of votes of the quorum are cast.
Recommendation Pending	Action taken if CORE requires minor additional information and / or modifications. Final recommendations may be given upon receipt of written confirmation that additions or modifications have been completed.
Deferral	Action taken if substantial modification is required or if insufficient information is at hand to judge the issue adequately. The issue is deferred. In order to receive recommendation for a deferred matter, it must be submitted again for a full CORE review at a subsequent, convened meeting, unless the Chair determines that expedited review is acceptable.
No Recommendation	No action taken if the majority of quorum casts dissenting votes which would not be altered by proposed modifications.

C. Sub-panels will be comprised of one or more voting members of the Council and Advisors as needed. These members and consultants will be requested to serve on Sub-panels on a rotating basis and utilized for expedited review of critical issues needing the immediate attention of the CORE.

- 1) The Chair and Vice-Chair, under the direction of the Chair, have authority to designate a Sub-panel of the Council.
- 2) A Sub-panel discussion may be convened at any time and may be comprised of one or more voting members of the Council and consultants as needed, selected by the Chair or the Vice-Chair, acting under the direction of the Chair.
- 3) The Sub-panel members may vote to “Recommend”, “Not Recommend” or for “Deferral”, and these recommendations will be provided in writing to the Chair.

D. Task Forces may be comprised of additional Council members, advisors, and consultants as deemed appropriate.

- 1) The Chair and Vice-Chair, under the direction of the Chair, have authority to designate a Task Force of the Council.
- 2) Task Force discussions may be convened at any time and may be comprised of one or more voting members of the Council and consultants as needed, selected by the Chair or the Vice-Chair, acting under the direction of the Chair.
- 3) The Task Force members may vote to “Recommend”, “Not Recommend”, or for “Deferral”, and these recommendations will be provide in writing to the Chair.

1.5 Recordkeeping Requirements

A. Generally

- 1)The CORE records shall include, but not be limited to: copies of all materials reviewed, meeting agendas and approved minutes, a list of CORE members, CORE written procedures, general communications files, and, until transcribed into paper format and accepted by the Council, the taped recordings of meetings.
- 2)The Recording Secretary, under the direction of the Chair, will maintain records for at least three years or for a time-period otherwise determined by the Chair or Vice-Chair for business or regulatory purposes.
- 3)The minutes of each meeting, taken by the recording secretary or her alternate, shall include a copy of the agenda, a list of all members attending the meeting, a summary of discussion and voting decisions on each issue. A taped recording of the meetings shall be retained until transcribed and the minutes approved by the Council.
- 4)The Chair shall determine the location for the CORE records.

B. Dissemination Requirement

It is the responsibility of the Chair with the assistance of the Council members to monitor the applicability, dissemination and implementation of research ethics information, including the CORE Intranet site.

1.6 Role of the Council

The Council will address a wide range of ethical issues regarding research and Quintiles. Quintiles Corporate Policy No. 003 establishes Quintiles' general policy regarding compliance and quality. A primary function of the Council is to monitor applicable laws, regulations, and guidelines, as they relate to ethical issues and research on a global basis. The Council is responsible for reviewing, recommending, and monitoring the implementation of specific policies and procedures by Quintiles, as needed, to address emerging issues within Quintiles related to research ethics and the protection of human subjects in research.

Should Quintiles as a Contract Research Organization seek to obtain accreditation for the protection of human subjects, a Task Force of a small number of CORE members shall be responsible for the application process and related activities in an ongoing basis. This Task Force may request assistance as needed from other CORE members / advisors, with approval by the CORE Chair.

1.7 Adoption and Amendment

The Council adopted the original CHARTER unanimously on **January 15, 2004**, and may amend the CHARTER from time to time, as it deems appropriate.