



## **Roche Framework for Discussing and Resolving Ethical Issues in Clinical Research**

### ***Introduction***

Roche has established a systematic framework for discussing and resolving potential ethical issues that may arise during the course of everyday work in drug development. This framework incorporates a central point of contact for Roche staff and an escalation process to facilitate review of alternative perspectives.

This process was formalized within Pharma Development, in July, 2003. By taking this action, Roche has assumed a leadership role among pharmaceutical companies by recognizing the importance of proper handling of ethical issues that may arise during drug development.

### ***Why is this process needed?***

The development of new drugs often opens new areas of science whose interface with social values and norms is uncertain. Ethics and integrity are central to the way in which Roche employees work, however there are times when employees can face grey areas, where the "right" decision is not always clear cut. The process Roche has put in place allows ethical issues to be raised early and resolved as quickly and efficiently as possible. It also provides a support mechanism for Roche employees, so they know that they need not face difficult issues alone, and can get independent advice.

### ***How and when might the process be used?***

Employees are always encouraged to discuss issues within their team and departments and resolve them as far as possible within the normal team decision-making processes. However, there are times when teams themselves may be split along differences of opinion on a topic, or when individuals within a team might feel uncomfortable.

### ***How does the process work?***

#### ***A three step approach***

##### ***I. Consultation with Global Ethics Liaison (chart 1)***

When ethical challenges cannot be resolved locally, individuals or teams can approach the Global Ethics Liaison, who is independent from the clinical development teams or departments. The Global Ethics Liaison is a central source for advice on issues involving ethics in clinical research, and can be contacted confidentially by any staff member. Through a process of fact-finding and consultation with peers and appropriate subject-matter experts, as needed, the Global Ethics Liaison will facilitate the team to come to a decision that is acceptable to all team members.

##### ***II. Escalation to internal committee of experts (chart 2)***

However, the complexity of an issue may be such that even after the initial consultation and discussion, the team remains divided or the individual still feels uncomfortable. This is a clear indication that further discussion is warranted.

The issue can then be taken, in confidence, to an internal committee of experts. This committee will include the Head of Pharma Development, the Head of the Clinical Quality Department, and other experts from within Roche. The exact composition of the committee is dependent on the actual issue under discussion. For example if the query involves a particular therapeutic area such as oncology, experts from that field will be included in the committee. The committee will hear the points of view of all parties concerned and voice an opinion, which will be communicated back to the team by the Global Ethics Liaison.

### ***III. Consultation with external advisory group (chart 2)***

If there is still discomfort, the internal committee may seek advice from an external advisory group, the Clinical Research Ethics Advisory Group (CREAG) to gain an external perspective. This committee includes outside experts from academia, bioethics, and sociology, but also non-specialists, such as representatives of patient advocacy groups. Global membership ensures that the advice provided is as comprehensive and relevant as possible. The internal committee will consider the advice of the CREAG and come to a final position. This will then become the Roche position on the issue, which will be communicated back to the team by the Global Ethics Liaison.

### ***Clinical Research Ethics Advisory Group (CREAG)***

As well as providing input in specific instances, the CREAG also keeps Roche updated on ethical issues from the wider health arena, and acts as a sounding board, by regularly participating in periodic ethics discussions with Roche. In addition, the CREAG will also monitor Roche's posting of trials on [www.Roche-Trials.com](http://www.Roche-Trials.com) to ensure that information on the website always accurately reflects the Roche Policy on Transparency in Clinical Trials.

### ***Raising awareness***

To promote awareness of the process, and to reinforce the company's corporate values and ethical standards, ethics education is offered to employees. During training sessions the benefit of open dialogue regarding potential ethical issues is stressed, and the concept of ethics and what it means to Roche employees in their daily work is explored.

Chart 1.

## Roche Framework for Discussing and Resolving Ethical Issues in Human Subject Research

### Initial Consultation with Global Ethics Liaison

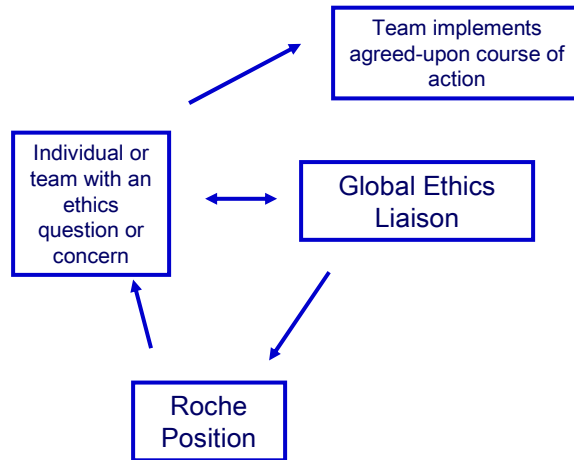


Chart 2.

## Roche Framework for Discussing and Resolving Ethical Issues in Human Subject Research

