Company Survey Responses

Company Size and Research Focus

The companies that responded ranged in size from 50 employees or less to over 50,000. They were involved in a wide range of research: genomics, molecular biology, bioinformatics, and pharmaceuticals were the most frequently mentioned. Some of the other research areas included biodefense, agriculture, environmental, materials science, nanotechnology, biochemical, structural biology, and devices.

The survey specifically presented nine categories of issues on which respondents were asked if they had received ethics advice.

Types of Issues on Which Companies had Received Ethics Advice

- Data collection, confidentiality, storage and/or disclosure (9)
- Relationships with media, customers, state/federal agencies, or general public (8)
- Potentially controversial research or product development (7)
- Product safety (7)
- Conflicts of interest (7)
- Clinical trials (6)
- Making products more beneficial and/or accessible to disadvantaged groups or low income countries (5)
- Post-marketing phase of product (4)
- Potential environmental impact (2)

In addition, five respondents identified other topics:

- Selection criteria for product development—which genes to focus on, how to communicate data, how to develop marketing materials to support product sales and descriptions.
- We have looked extensively at empowering consumers with information and access to products currently controlled and limited by health care professionals.
- Broad discussion on the uses and ethics surrounding human clinical materials and information.
- Proper use of technology by customers (are there customers to whom we will not sell technology?); race and genetics.
- Center of origin/center of biological diversity; acceptance of new technologies in different cultures; guidance in long-term technology research; and gene switches/gene use restriction technology.

Under each of the survey's nine categories, we asked respondents to be more specific about the types of issues that prompted them to seek advice. The most frequently identified issues are noted below.

Data collection, confidentiality, storage, and/or disclosure

- Maintenance of anonymous or personally identifiable data (7 of 9)
- Compiling or storing genetic, medical, or other sensitive information in data banks (6 of 9)
- Disclosure of data (e.g., to insurers, press, university researchers, scientific journals, patients and/or their families, and affect consumers) (6 of 9)
- Integrity of data and accuracy of interpretation (5 of 9)
- Collecting data from human research participants or affected parties in the pre- or post-marketing phases (4 of 9)

Relationships with the media, customers, state or federal agencies, or the general public

- Developing informational materials for products (6 of 8)
- Plans for direct to consumer marketing (4 of 8)

Potentially controversial research or product development

- New medications or medical devices (3 of 7)
- Other issues (4 of 7)

Product safety

- Assessment of benefits and risks for human or animal health (4 of 7)
- Safety data available from pre-marketing studies (4 of 7)
- Labeling of product (3 of 7)

Conflicts of interest

- Efforts to develop procedures to identify and manage conflicts (6 out of the 7)

Clinical trials

- Procedures to assure adequate protections for subjects in the trial (5 of 6)
- Assistance with documentation and preparation for IRB review (4 of 6)
- Benefits and/or payments to research subjects (4 of 6)

Making your products more beneficial and/or accessible to disadvantaged groups or low income countries

- Developing products relevant to the needs of underserved groups generally or low-income countries (3 of 5)
- Developing or marketing products appropriate to the needs of particular groups (3 of 5)

Post-marketing phase of your product

- Whether, and if so how, to proceed with a post-marketing trial (e.g., determining whether the potential advantage of one product over another justifies additional human research) (3 of 4)
- New information about a product's increased or reduced effectiveness (3 of 4)
- Changes in labeling (3 of 4)

Potential environmental impact

- Disposal or storage of wastes (2 of 2)

The survey asked about the types of ethics consultants used, their professional background, the types of advice sought from both external and internal consultants, how that advice was kept, how helpful the advice was, and how it was used. Responses to these questions are tabulated below.

Types of ethics consultants used

- Internal ethics consultant on staff (7)
- External ethics consultant for a specific issue or short-term engagement (6)
- External institutional review board (5)
- In-house legal counsel (5)
- External ethics consultant(s) on annual or long-term retainer (4)
- Internal ethics advisory committee (3)
- External ethics advisory committee (2)
- External legal counsel (3)
- Ethics advisory committee composed of internal and external experts (1)
- Internal institutional review board (1)

Professional backgrounds of ethics consultants

- Medical professional (9)
- Philosopher/Bioethicist (8)
- Physical/life scientist (5)
- Lawyer (5)
- Social scientist (3)
- Religious scholar/clergy (3)

Types of advice sought from external ethics consultants

- Designing/Implementing solutions to problems (9)
- Identifying potential problems before they arise (9)
- Addressing existing or emerging problems (7)

Types of advice sought from internal ethics consultants

- Designing/Implementing solutions to problems (8)
- Identify potential problems before they arise (8)
- Addressing existing or emerging problems (7)

Records of advice

- Notes of oral advice provided by consultants (7)
- Written advice provided by consultants (6)
- Transcript of oral advice (0)
- No records kept (0)

How helpful has the ethics advice been?

On a scale of 0 to 10, where 0 is “not very helpful” and 10 is “extremely helpful,” the average score was 9.

How advice was used by the company

- Incorporated into company policy (10)
- Used to inform decision-making (9)
- One time application only to an immediate problem (5)
- Still under consideration by company (0)
- Not used (0)

The respondents were also asked how often their companies had conferred with ethics consultants during the past year, how the consultants were compensated, and whether confidentiality nondisclosure agreements were signed, information shared, and problems or disputes arose. Finally, the respondents were asked about the existence of policies or guidelines for consultants. Responses to these items are summarized below.

Frequency of conferring with ethics consultants in the last 12 months

- 6-20 times (4)
- 1-5 times (3)
- 20+ times (3)

Consultant compensation

- Hourly rate (4)
- Salaried staff (3)
- Per consult fee (3)
- Not compensated (2)
- Annual fee (0)
- Retainer (0)
- Stock (0)
- Stock options (0)

Consultant expenses

- Reimbursed (6)
- Not reimbursed (4)

Confidentiality nondisclosure agreements for external consultants

- Consultants required to sign (8)
- Consultants not required to sign (1)

Sharing company information with consultants

No instances of not sharing were reported

Problems or disputes with ethics consultants

Only one company reported a problem—an external consultant who disclosed confidential information to a customer

Company policies or guidelines for using external consultants

- Policy in place (5)
- No policy (5)