

# Consultant Survey Responses

The survey began with several questions aimed at learning more about the consultants and the companies for which they consulted. Questions were asked to determine how many companies they consulted for, their motivation for doing such consulting, the types of companies they advised, their professional training, and their primary employer. Their responses are as follows.

## **Number of biotechnology companies consulted for**

- 2-4 (11)
- 1 (6)
- 5+ (3)

## **Reasons for agreeing to consult**

- Intellectual challenge associated with the issue for which advice was sought (19)
- Considered it a social/professional responsibility (16)
- To help company do the “right thing” (15)
- Opportunity to engage in “hands-on” ethics advising (13)
- Previous relationship with company or its personnel (7)
- Other (4)
  - All my advising on ethics has been part of consulting on larger strategic issues for these companies.
  - You forgot to include ‘for the money,’ which really should be in your list. I do not think we should be ashamed of being paid for our expertise.
  - Income -- I don’t do it for free.

## **Types of companies**

- Large established company (over 500 employees) (11)
- Start-up (10)
- Small established company (under 100 employees) (10)
- Mid-sized established company (100-500 employees) (4)
- Unsure (1)

## **Scope of the companies’ business operations**

- National (16)
- Multi-national parent company (6)
- Regional (2)
- Local (1)
- Subsidiary or unit of a multi-national (1)

- Unsure (1)

**Areas of research or product development in which company(ies) were engaged**

- Genomics (9)
- Pharmaceuticals (8)
- Biology (5)
- Bioinformatics (2)
- Devices (2)
- Agricultural (1)
- Other (7)
  - Gene based diagnostics
  - Stem cell research, including use of somatic cell nuclear transfer and parthenogenic activation of oocytes
  - Blood products
  - Human application of disease management strategy
  - Tissue generation
  - Stem cells
  - Stem cells; therapeutic cloning

**Professional training of consultants**

- Philosophy/Ethics (11)
- Medicine or other health care field (6)
- Social science (5)
- Physical or life sciences (3)
- Law (2)
- Religious studies/theology (2)
- Other (1)
  - business

**Consultant's primary employer**

- College or university (17)
- Self-employed (1)
- Other (3)
  - Retired college professor
  - Research institute
  - Non-government organization (at the time of initiation of service with the company in question, I was affiliated with a college. Now I am considered a "community member" of the Ethics Advisory Board).

### **How consulting work was arranged**

- Directly through me (consultant) (18)
- Through a secondary affiliation (4)
- Through my primary employer (3)
- Other (2)
  - Colleague at another university
  - At the time of initiation of service with the company in question, a colleague and I together developed a relationship with the company; he started the Ethics Advisory Board and I decided to participate.

The next two questions focused on the resources consultants used when considering their roles and responsibility as a consultant for the company(ies) and the types of ethical issues for which their advice was sought.

### **Resources used to consider their role and responsibility as a consultant for industry**

- Academic training (19)
- Guidance from colleagues (12)
- Law or other legal resources (10)
- Literature related to consulting (7)
- Codes of conduct for professionals in your field (3)
- Specific code of conduct for consultants (1)
- Other (6)
  - National Bioethics Advisory Commission (NBAC), various committees at NIH, NLB, DOE on genome work ethics, literature on ethics in genetics, my own research
  - Bioethics literature regarding human embryo research
  - Ongoing discussion with others on the team of consultants
  - 1. Bioethics training course 2. Practice of a hospital ethics committee
  - Previous federal consulting experience
  - University policies

### **Types of ethical issues for which advice was sought**

- Potentially controversial research or product development (19)
- Data collection, confidentiality, storage, and/or disclosure (15)
- Conflict of interests (10)
- Design or conduct of clinical trials (10)
- Company's relationships with the media, customers, state or federal agencies, or general public (9)
- Accessibility of products (experimental or approved) to disadvantaged groups or low income countries (8)
- Product safety (5)
- Post-marketing phase of product (3)

- Environmental impact (2)
- Other ethical issues (6):
  - Issues in human embryo and stem cell research
  - Informed consent; work in other countries
  - Marketing practices
  - Informed consent for a non-trial-related medical procedure
  - Philosophical issues dealing with human nature. Theological issues arising from forecasts of increased longevity and improved human health. Research protocol advisability.
  - Women's autonomy for participation in/compensation for potentially risky and painful research, with strong focus on consent, competency, and related issues.

The next set of questions sought information on to whom in the company they reported, the types of advice requested from them and the form in which it was given, how their advice was used, and how useful to the company they thought it was.

### **To whom they reported**

- CEO (14)
- Director/VP for research (11)
- Member, company board of directors (3)
- Legal counsel (2)
- Director of Public Affairs/Public Relations (2)
- Ethics officer (1)
- Director of governmental affairs (1)
- Director of human resources (1)
- Other (3)
  - Program manager
  - There was no formal "reporting" procedure - this was an unusual and possibly unique largely autonomous ethics committee.
  - Not sure how to answer this; I am on an Ethics Advisory Board who really reports to no one. We most closely communicate with the President and CEO.

### **Types of advice requested**

- Identify potential problems before they arise (19)
- Address existing or emerging problems (14)
- Designing/implementing solutions to problems (12)
- Other (3)
  - Develop code of ethics
  - Provide oversight for a controversial research program
  - Serves as sounding board for key individuals in company

### **Form in which advice was transmitted to company**

- Both (16)
- Verbal (4)
- Written (0)
- Other (2)
  - Discussions at meetings of Ethics Advisory Board
  - Extensive scholarly research papers on the topic

### **How company(ies) used the consultant's advice**

- Advice incorporated into company policy (15)
- Advice only used as a one-time application to a specific issue (10)
- Advice has not been used (3)
- Advice still under consideration by company (2)
- Don't know (7)

### **How useful the consultants thought the advice was for the company(ies)**

On a 10-point scale, where 0 was “not at all useful” and 10 was “extremely useful,” the average score was 8.

The next series of questions dealt with financial arrangements between the consultant and company(ies), including reimbursement for expenses and compensation for their consulting work.

### **Reimbursement for expenses**

- In every case (13)
- Sometimes (6)
- Never (2)

### **Whether consultants were offered a fee, and accepted or declined it**

- Offered a fee in every case and accepted (7)
- Sometimes offered a fee and accepted when offered (4)
- Sometimes offered a fee and sometimes accepted (3)
- Offered a fee in every case and sometimes accepted (2)
- Never offered a fee (2)
- Sometimes offered a fee, but never accepted (1)

### **Whether a portion of any fee accepted was given directly to their employer**

- Sometimes (2)
- In every case (1)
- Never (14)

### **Type and range of any compensation**

- Per consult fee (9)
- Hourly rate (5)
- Stock options (3)
- Not applicable (3)
- Annual fee (1)
- Retainer (1)
- Stock (0)
- Other (6)
  - Per meeting (\$500/meeting, where meetings lasted 3 days)
  - Daily rate
  - Portion of salary paid
  - Per meeting \$200 to \$500
  - My consulting income was not tied in any way to the profitability of the company. In order to protect the independent judgment of the ethicists as well as the company's relationship to the Securities and Exchange Commission, we clearly set parameters in advance to prevent conflict of interest or inducement to compromise in favor of the company's business interests.
  - We have been offered the NIH per diem rate of \$250 per day of service. I don't know if you consider this to be a "fee" or not.

Hourly rates were reported in the range of \$125-200; daily fees from \$200-1,000.

Several questions then were asked about the requirements associated with any agreement made with the company(ies), including whether they signed a formal written agreement/contract to govern the terms of their consulting work for the company and whether a confidentiality/non-disclosure provision or non-compete provision were agreed to.

### **Written agreement/contract with company(ies)**

- Sometimes (8)
- In every case (8)
- Never (5)

### **Confidentiality/non-disclosure provision**

- In every case (9)
- Sometimes (6)
- Never (4)

### **Non-compete provision**

- Never (19)
- Sometimes (1)
- In every case (1)

Whether there were difficulties in consultants gaining access to company information was the topic of the next several questions along with whether they had experienced disputes with a company(ies) during their consulting work.

### **Company(ies) unable to share information requested by consultant**

- No (17)
- Yes (4)

### **If yes, reasons for not providing the information**

- Proprietary information (2)
- Information not available (1)
- Information company did not feel comfortable disclosing (1)

### **If yes, withholding information adversely affected the consultant's work**

- No (3)
- Yes (1)

### **Disputes with the company(ies)**

- No (15)
- Yes (5)

### **If yes, nature of the dispute**

- Consultant refused to testify in a lawsuit.
- Company requested that published findings be retracted.
- Disagreement over whether a particular experiment should be performed.

The final question asked respondents to list the “top three opportunities and pitfalls associated with ethics consulting for biotech companies.” The following lists of responses are an edited summary of what was written by the respondents.

### **Opportunities**

- Promoting inclusion of ethical considerations in making business decisions, which is a service to society. (9)
- Practicing profession in real-world situations and exerting influence on research. (7)
- First hand knowledge of impending scientific developments. (7)
- Building relationships with others working in then same field, including scientists, biotech managers, industry officials, and other consultants. (5)
- Unique insight into the workings of industry that academics rarely have. (5)

### **Pitfalls**

- Being used as an “ethical cover” for public relations and to rubber stamp decisions. (7)
- Getting co-opted by: (1) being paid to consult, and (2) the prestige of working for corporate clientele—which may cloud critical judgment. (7)
- Unwanted exposure to mass media, which frequently misinterpret what was said and reduces everything to sound bites. (2)
- Peer criticism for “selling out.” (4)
- Client-imposed restrictions on publication. (2)
- Drain on time for other activities, including teaching and research. (3)

**Disclosure: One of the project’s co-directors (MSF) is on an ethics advisory board for a multi-national pharmaceutical company. He did not participate in the survey.**