



AAAS Survey of Biotechnology Companies

This survey is part of a study examining the policies and practices related to ethics consulting for the biotechnology industry. The American Association for the Advancement of Science (AAAS) is interested in learning more about the mechanisms and resources on which companies, researchers, scientists, and others rely when assessing courses of action in response to the ethical and social issues raised by advances in medical, agricultural, and biotechnological research. A central part of this phase is a survey of biotechnology companies designed by AAAS staff to: (1) identify the types of issues that have led companies to engage consultants, and (2) identify the practical issues that they have encountered in seeking and using advice on ethical issues.

Individual responses will be treated as confidential. The data collected will be reported and made public only in an aggregate form. Individual responses will not be linked to individual companies nor to individual respondents.

In order to protect the confidentiality of the respondents, survey responses will be issued an identifying code number. In accordance with responsible data storage practices, the identifying code information will not be stored with the response data. Any individually identifying information will be stripped from survey responses.

In some instances, the survey may be sent to several individuals at the same company. Although this may produce variance among the company's responses, we encourage each person who received a survey to respond. Since this survey is intended to gather qualitative information, we chose to oversample in cases where multiple respondents were identified. We believe this approach will provide the most complete picture of current practices in the field. Should you have questions about this, or any other any aspect of the survey, please contact the project research director, Brent Garland, by phone at 202.326.7016 or by email at dbgarlan@aaas.org.

If, after reviewing the survey, you would prefer to respond by phone, you may contact Kevin Alleman to schedule an interview time convenient to you. He can be reached at 202.326.6606 or kallema@aaas.org.

We ask that you return the survey to biosurvey@aaas.org (or participate in a phone interview) by March 15, 2005. We look forward to hearing from you, and appreciate your assistance in this effort.

This survey is interested in advice on ethical issues related to researching, developing, testing and disseminating the company’s products and processes ONLY, and not with business matters (such as accounting practices or hiring and firing policies) that may raise ethical issues. Please respond by considering only the advice sought or received in regard to the company’s research and development mission.

There are a few terms used in the survey that require definition. Those terms are:

Ethics Advisory Committees (internal or external) are bodies convened by the company for any of the following (or similar) purposes: providing advice on questions of ethical or social import; setting ethics policies or guidelines; or reviewing policies, procedures or research for potential ethical issues.

Ethics Consultant (internal or external): A person who is specifically approached by the company for advice on ethical issues, regardless of his/her training or position. Ethics consultants could be involved in any of the following (or similar) activities: providing advice on questions of ethical or social import; setting ethics policies or guidelines; or reviewing policies, procedures or research for potential ethical issues.

Internal (as used in the context of ethicists, consultants, advisory boards, etc.). “Internal” refers to those persons who are considered to be full- or part-time (but not temporary) employees of the company. Staff members who sit on internal advisory boards, who are the ethics officers for labs, and in-house legal counsel would all be considered to be “internal” persons.

External (as used in the context of ethicists, consultants, advisory boards, etc.). “External” refers to persons who, while possibly compensated by the company, would not consider their primary employer to be the company, or those whom the company would not classify as internal employees (as defined above). External persons may have long-term relationships with the company and still be considered to be external (e.g., a professor on multi-year retainer). In addition, external persons may have substantial duties to the company and still be considered external (e.g., duties imposed by contract or retainer agreement). Short-term consultants, university faculty contracted to consult, and law firm counsel would all be considered “external” persons.

GENERAL QUESTIONS

1a) In the past calendar year, how many people did your company employ? _____

1b) What percentage of these employees are full time employees? _____

2a) Please list the type(s) of research conducted by your company? (Mark all that apply)

___ Agricultural (animal, plant, GMOs)
___ Biochemical
___ Biodefense
___ Bioinformatics
___ Environmental

___ Genomics
___ Molecular Biology
___ Structural Biology
___ Material Science
___ Composite Materials

- Nanotechnology
- Nanomechanics
- Nanochemistry
- Other (please describe)

- Polymer Chemistry
- Pharmaceuticals
- Devices

ETHICS QUESTIONS

*The lists of items following each question are not intended to be exhaustive. Feel free to include issues that may not have been addressed within the confines of these lists. **Please answer the following questions with regard to your research and development mission.***

3a) Has your company received advice on ethical issues related to **conflict of interests**?

(Mark one) Yes No

3b) If YES, which of the following describe the issue(s) that prompted you to seek advice? (Mark all that apply)

- Company staff or officers have external roles that may potentially compete with the interests of the company, such as serving on advisory committees
- Disclosure of possible conflicts of clinical researchers (e.g., stock options)
- Efforts to develop procedures to identify and manage conflicts
- Other (please specify):

4a) Has your company received advice on ethical issues related to **data collection, confidentiality, storage, and/or disclosure**?

(Mark one) Yes No

4b) If YES, which of the following describe the issue(s) that prompted you to seek advice? (Mark all that apply)

- Maintenance of anonymous or personally identifiable data

- Collecting data from human research participants or affected parties in the pre- or post-marketing phases
- Compiling or storing genetic, medical, or other sensitive information in databanks
- Disclosure of data (e.g., to insurers, press, university researchers, scientific journals, patients and/or their families, and affected consumers)
- Integrity of data and accuracy of interpretation
- Other (please specify):

5a) Has your company received advice on ethical issues related to **potentially controversial research or product development**?

(Mark one) Yes No

5b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- Genetically modified/engineered agricultural products
- Genetically modified/engineered animals or organisms
- New medications or medical devices
- Human stem cell applications or cloning
- Developing products aimed at a specific ethnic or racial group
- Introducing products with potential risks to vulnerable groups (e.g., children, elderly)
- Use of data in marketing products not regulated by the government (e.g., vitamins, nutritional supplements)
- Other (please specify):

6a) Has your company received advice on ethical issues related to **making your products more beneficial and/or accessible to disadvantaged groups or low income countries**?

(Mark one) Yes No

6b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- Including subjects from diverse racial and ethnic backgrounds in clinical trials
- Developing products relevant to the needs of underserved groups generally or low-income countries
- Making donations of products to low income groups or countries
- Developing or marketing products appropriate to the needs of particular groups
- Other (please specify):

7a) Has your company received advice on ethical issues related to **relationships with the media, customers, state or federal agencies, or the general public?**

(Mark one) Yes No

7b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- Timing of the public release of product information
- Responding to consumer complaints
- Developing informational materials for products
- Disclosure of potential side effects not evident in clinical trials
- Plans for direct to consumer marketing
- Other (please specify):

8a) Has your company received advice on ethical issues related to **clinical trials?**

(Mark one) Yes No

8b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- Assistance with documentation and preparation for IRB review
- Selection or recruitment of subjects

- Procedures to assure adequate protections for subjects in the trial
- Benefits and/or payments to research subjects
- Potential clinical trials in a developing country
- Other (please specify):

9a) Has your company received advice on ethical issues related to the **post-marketing phase of your product**?

(Mark one) Yes No

9b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- 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)
- New information about a product's increased or reduced effectiveness
- New information about possible adverse effects
- Promoting or restricting new (off-label) uses of the product
- Changes in labeling
- Other (please specify):

10a) Has your company received advice on ethical issues related to potential **environmental impact**?

(Mark one) Yes No

10b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- Affect of production process or product on surrounding environment/habitat/organisms (e.g., release of genetically modified/engineered plants or organisms)
- Disposal or storage of wastes
- Source or acquisition of raw materials
- Other (please specify):

11a) Has your company received advice on ethical issues related to **product safety**?

(Mark one) Yes No

11b) If YES, which of the following types of issue(s) prompted you to seek advice? (Mark all that apply)

- Assessment of benefits and risks for human or animal health
- Recall of product
- Labeling of product
- Safety data available from pre-marketing studies
- Safety data available from post-marketing studies
- Other (please specify):

12a) Has your company received advice on **other ethical issues**?

(Mark one) Yes No

12b) If YES, please briefly describe the issue(s) that prompted you to seek advice.

13) If you responded YES to at least one of the “a” items above (3a, 4a, 5a, 6a, 7a, 8a, 9a, 10a, 11a, 12a), have the ethics consultants been (Mark all that apply):

*For definitions of “internal” and “external” please refer back to page 2

- Internal ethics consultant on staff
- External ethics consultant(s) on annual or long-term retainer

- External ethics consultant for a specific issue or short-term engagement
 - Internal ethics advisory committee
 - External ethics advisory committee
 - Ethics advisory committee composed of internal and external experts
 - Internal institutional review board
 - External institutional review board
 - In-house legal counsel
 - External legal counsel
 - Other (please specify):
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14) What are the professional backgrounds of your ethics consultants? (Mark all that apply)

- Physical or Life scientist
 - Social scientist
 - Philosopher/ Bioethicist
 - Lawyer
 - Religious scholar/ Clergy
 - Medical professional
 - Other (please specify):
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15) What types of advice have you sought from external ethics consultants? (Mark all that apply)

- Identify potential problems before they arise
 - Address existing or emerging problems
 - Designing/Implementing solutions to problems
 - Not applicable
 - Other (please specify):
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16) What types of advice have you sought from internal ethics consultants? (Mark all that apply)

- Identify potential problems before they arise
- Address existing or emerging problems
- Designing/Implementing solutions to problems

- Not applicable
 - Other (please specify):
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17) In what form(s) have records of advice been kept? (Mark all that apply)

- Written advice from consultant(s)
- Transcript of oral advice
- Notes on oral advice
- Other
- No records kept

18) Overall, how helpful has the ethics advice received by your company been? Please assign a value between "0" and "10," where 0 is "Not at all helpful" and 10 is "Extremely helpful"

19) Generally, how has the advice that your company has received from ethics consultants been used? (Mark all that apply)

- Advice incorporated into company policy
 - Advice only used as a one-time application to an immediate problem
 - Advice used to inform decision making
 - Advice still under consideration by the company
 - Advice has not been used
 - Other (please specify):
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20) In the last 12 months, approximately how many times did your company confer with an ethics consultant(s)? (Mark the correct range)

1-5 times 6-20 times More than 20 times

21) How have your ethics consultants been compensated? (Mark all that apply)

Also, please indicate the general range of compensation per consultant (e.g., \$100/hr., \$2000/yr., option on 10,000 shares yearly, etc.)

- Not compensated _____
- Salaried staff _____
- Per consult fee _____

- Hourly rate _____
- Annual fee _____
- Retainer _____
- Stock _____
- Stock options _____
- Other (please specify) _____

22) Were the expenses of external ethics consultant(s) reimbursed?

(Mark one) Yes No

23) Are external ethics consultants required to sign confidentiality nondisclosure agreements?

(Mark one) Yes No

24) Have there been instances where the company was unable to share information requested by the external ethics consultant?

(Mark one) Yes No

25) If you responded YES to item 24 above, then please indicate the types of requests from consultants where sharing information was not possible (Mark all that apply).

- Requested information that would reveal proprietary information (e.g., trade secrets or marketing strategies)
- Requested information that was confidential (e.g., that potentially could identify a clinical trial participant)
- Requested information that was not available
- Requested information that company did not feel comfortable disclosing
- Requested information that could not be made available on advice of counsel
- Not applicable
- Other (please specify)

26) Have you encountered any problems or disputes with ethics consultants over their work, advice, or final products (e.g., consultants publicly speaking out prematurely; receiving unexpected media exposure; unauthorized disclosure of information)?

(Mark one) Yes No

If YES, please describe briefly your experience:

27) Does your company have specific institutional policies or guidelines in place governing the company's general use of outside consultants (not necessarily ethics consultants)?

(Mark one) Yes No

If possible, please forward a copy when returning this survey. (Any materials submitted will be stored separately from the response data.)

Thank You