

An IBC and Biosafety Program Benchmarking Survey

Christine M. Johnson and Karen M. Dobos

Research Integrity & Compliance Review Office, Colorado State University, Fort Collins, CO



Introduction/Objectives

Vast differences in the size, scope, and needs of institutions which conduct research involving biohazardous materials results in vast differences among Institutional Biosafety Committees (IBCs) and biosafety programs. A benchmarking survey was conducted of IBC and biosafety programs in an effort to identify common practices in the field, and to compare this information with that of Institutional Animal Care and Use Committees (IACUCs) and Institutional Review Boards (IRBs).

Primary objectives of the survey included:

- Assessing the organizational structure of IBC and biosafety programs
- Determining the scope of IBC review
- Comparing the size of IBC and biosafety programs

Methods and Results

The survey consisted of 24 questions regarding the organizational structure of the institutional bioethics committees (IBC, IACUC, and IRB) and biosafety officers, the scope of IBC review, how IBCs conduct their review, what events trigger a laboratory audit, the number of protocols reviewed by each of the bioethics committees, and the number of full-time employees (FTE) dedicated to support each of the bioethics committees and biosafety program. Demographic questions such as the type of institution (academic, government, hospital, private, or other), as well as total research expenditures (in 2016) for the institution, were also asked. Contact information for IBCs registered with the National Institutes of Health (NIH), Office of Science Policy (OSP) was obtained through a Freedom of Information Act (FOIA) request (August 2017). An invitation to participate in the survey was emailed to IBC contacts and posted on the ABSA listserv, and included a link to the web-based survey (created in Google Forms). Survey results were analyzed using Microsoft Excel.

157/1157 responses were received resulting in a response rate of 13.6%. Data is presented as the percent of respondents answering a specific question, unless otherwise stated.

Demographic Information

Table 1a. Type of research institution

Type of Institution	% of Respondents*
Academic	74.4%
Private	12.2%
Hospital	6.4%
Government	3.8%
Non-profit	2.6%
Biopharma company	0.6%

Table 1b. 2016 Total research expenditures

Research Expenditures \$	% of Respondents**
0-1M	10%
1.1-10M	11%
11-100M	29%
101-500M	31%
501M-1B	14%
>1B	5%

*Percentages based on 156 responses.

**Percentages based on 100 responses; 24 respondents indicated "do not know" and were removed, and 33 respondents left this question blank

Organizational Structure of IBC and Biosafety Programs

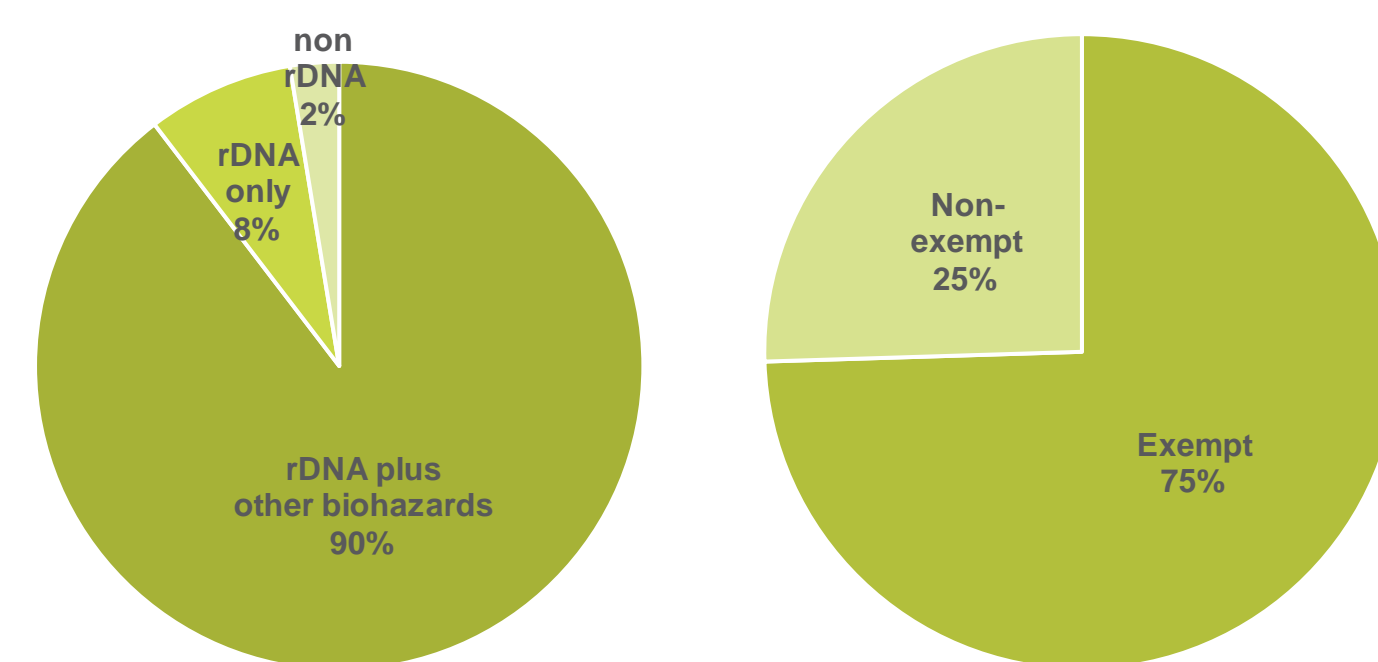
Table 2. Which administrative unit does your IBC, BSO, IACUC, and IRB report to?

Administrative Unit	IBC	BSO	IACUC	IRB
Vice President/Chancellor for Research	44.5%	15.5%	50.3%	50.3%
Environmental Health and Safety	19.4%	60.6%	0.6%	0.6%
Research Integrity and/or Compliance Office	19.4%	7.1%	23.9%	24.5%
Other	7.7%	8.4%	7.1%	8.4%
President/CEO	5.2%	3.2%	4.5%	3.2%
Sponsored Programs	3.2%	0.6%	5.2%	4.5%
None	0.6%	4.5%	7.7%	7.1%
External	0.0%	0.0%	0.6%	1.3%

There were 58 different reporting combinations; the three most common placed the IBC under the same administrative unit as the IACUC and/or IRB (either under VPR/VCR or Research Integrity/Compliance) and the BSO either in EHS or with the IBC in VPR/VCR. Percentages based on 155 responses.

Scope of IBC Review

Figure 1. Types of research reviewed by IBCs



8% of respondents reported that their IBCs only review rDNA research as articulated by the NIH Guidelines, while 90% indicated reviewing other biohazards in addition to rDNA research. The majority of IBCs (75%) also required registration/approval of research that is exempt from the NIH Guidelines.

Figure 2. Types of biohazards reviewed by IBCs

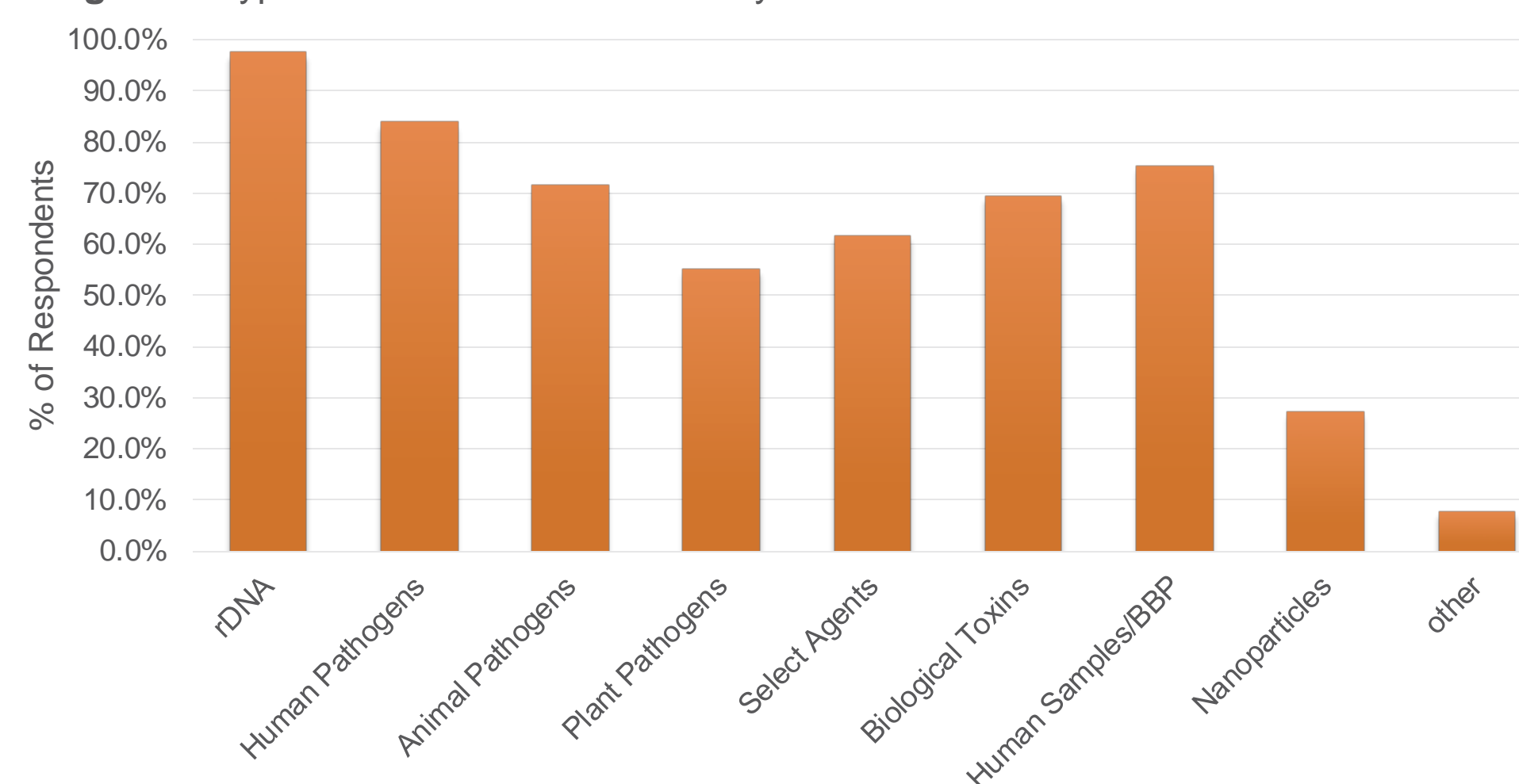
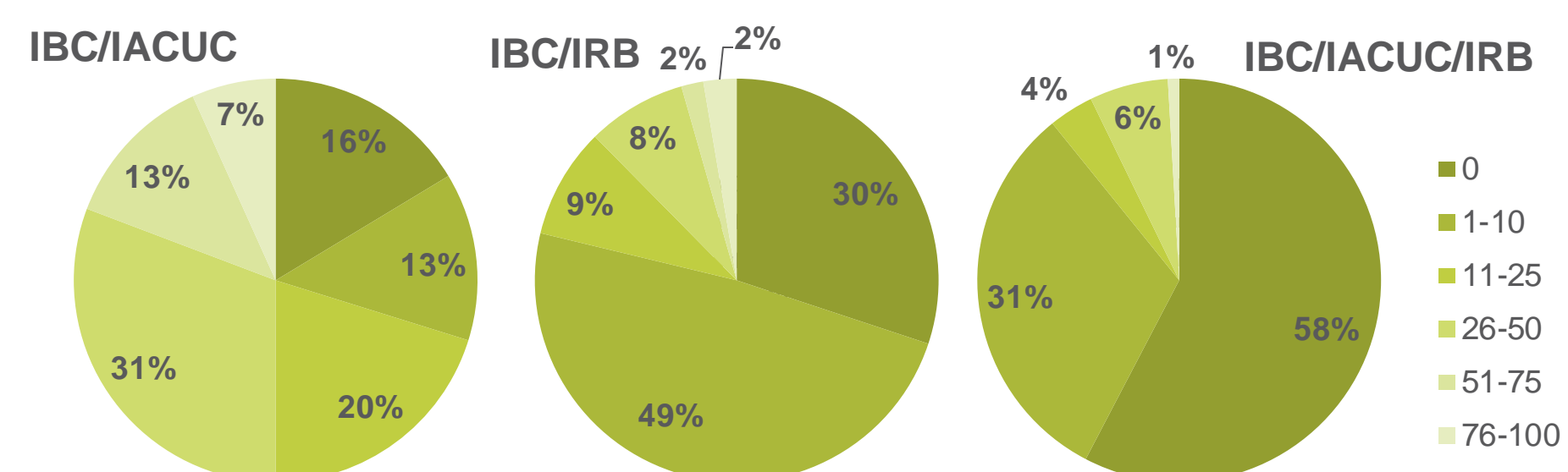


Figure 3. Protocols requiring review from multiple committees



Percentage of respondents reporting the number of protocols (from 1 to 100) requiring review by more than one committee.

66% of the respondents indicated conducting IBC review/approval on an individual project basis, whereas 21% indicated a PI/program based review/approval system, and 13% indicated using both.

The majority of respondents indicated laboratory audits were triggered by routine checks (59%) and new protocol submissions (20%).

Size of IBC and Biosafety Programs

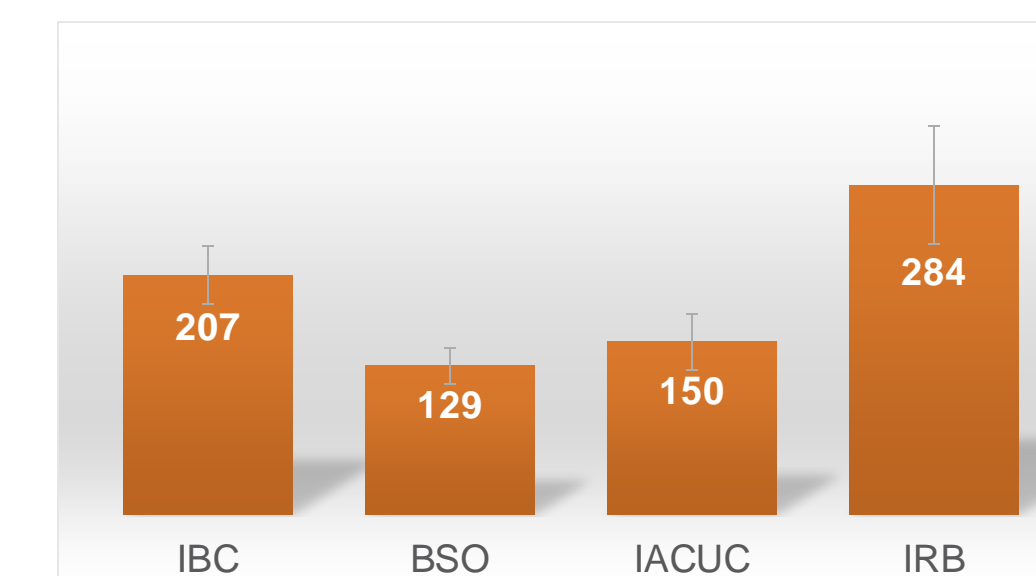
The number of protocols reviewed by each of the bioethics committees (IBC, IACUC, and IRB), ranged from less than 10 to several hundred for each committee, with a few institutions (2% for IBC, 5% for IACUC, 26% for IRB) reporting protocol numbers in the thousands.

Table 3. Number of FTE dedicated to support IBC, BSO, IACUC, and IRB

# of FTE	IBC	BSO	IACUC	IRB
0	22%	8%	7%	10%
< 1	20%	10%	8%	6%
1	40%	42%	33%	20%
1-2	14%	23%	27%	16%
> 2	3%	18%	26%	49%
# of Respondents	147	146	119	107

Percentage based on the number of respondents indicated for each committee.

Figure 4. Average number of protocols/FTE



Side note: Institutions with BSL3/select agent research had an average of three BSO FTE compared to one BSO FTE at institutions without these types research. However, the average number of IBC FTE remained at one regardless of whether or not BSL3/select agent research was conducted.

The number of FTE normalized to the number of protocols (i.e., # of protocols/# of FTE) for each institution. Data are shown as the mean ± SEM.

Discussion/Conclusions

The survey was well received, with many participants requesting the final results. While the survey further demonstrated the diversity among IBCs and biosafety programs, there were some commonalities that emerged. In assessing the organizational structure of IBCs and biosafety programs, the survey data revealed that IBCs most commonly reside under the same administrative unit (Vice President/Chancellor for Research) as the IACUC and IRB (Table 2), while most Biosafety Officers (BSOs) typically report to a different unit (Environmental Health and Safety). The proximity of IBCs to the other bioethics committees (IACUC and IRB) can be beneficial to the IBCs and assist in facilitating a coordinated review process, particularly for protocols requiring review from more than one committee (Figure 3), however, the separation from the BSOs is concerning and could result in a duplication of effort and added administrative burden if not well coordinated. Furthermore, the survey demonstrated that most IBCs have been tasked with far more oversight duties than originally prescribed by the NIH Guidelines (Figure 1), and as a result many IBCs have become more of a general biohazards review committee (Figure 2). Given these added responsibilities, it is interesting to note that most institutions reported having fewer FTE dedicated to support their IBC compared to the other bioethics committees, with 22% of respondents indicating having no staff to support the IBC and 60% of respondents indicating having one or less (i.e., part-time) FTE for IBC support. This discrepancy could be due to the higher average protocol numbers for IRBs (1137) and IACUCs (360), compared to IBCs (216), therefore necessitating more IRB and IACUC FTE. However, when the number of FTE was normalized to the number of protocols for each institution, we see that on average, each IBC FTE manages approximately 200 IBC protocols, whereas each IRB FTE manages about 280, and each IACUC FTE manages about 150. Further investigation would be required to determine if there is a true gap in IBC support staffing.

Outcomes

- Several similarities and shared practices among IBCs and biosafety programs were discovered.
- The data collected can be used by institutions as a tool to compare the organizational structure, scope, and size of their program to other programs.
- The benchmarking survey identified expanded review of scope of IBCs beyond the NIH Guidelines.