

Study of Affiliation Agreements Used by Institutions to Comply with the Requirements of Their Misconduct Assurance

All organizations that apply for or receive Public Health Service (PHS) funding are required by regulation (42 CFR Part 50, Subpart A) to have, among other things, an administrative process that meets the requirements of the regulation for dealing with allegations of scientific misconduct. They are also required to submit an annual report to ORI, which includes aggregate information on allegations, inquiries, and investigations, as well as information related to the institution's misconduct policies.

Of the approximate 3,700 institutions that have active assurances with ORI, a small number have established what has been described as "affiliation relationships" with other institutions, which has helped to streamline the institutional reporting requirement by allowing one institution, the "parent," to submit a consolidated annual report on misconduct activity to ORI for itself and the related "affiliates." However, the annual report has failed to capture what additional steps, if any, have been taken to insure that an administrative procedure has been established for dealing with misconduct that takes into account the consolidated relationships.

The purpose of this study was to evaluate whether these organizational units have policies that complied with the regulation, whether the affiliation arrangement was endorsed by all institutions, and whether the affiliation arrangement was feasible.

There have been a small number of officials within the study group who have stated that the term "affiliate" was not an accurate description of the institutional relationships within its group. The organization may be a division of the parent, or a wholly-owned subsidiary, for example. This clarification is noted. However, for the purpose of simplicity and consistency in this study, the contact organization for each of the groups will be referred to as the "parent," and each of the organizations represented by the "parent" will be referred to as an "affiliate."

SAMPLE

Initially, 86 institutional groups were identified for this study, which included 86 "parents" and 192 "affiliates." For varied reasons, 13 of the initial "parents" were removed from the study; some institutions declined to respond to the request for policies, some were consolidated with other institutions or went out of business, and some institutions terminated the parent/affiliate relationship. The remaining 73 "parents" and 178 "affiliates" form the basis of this study

Table 1 - Summary of Institutional Sample

Number of Parent/Affiliate groups	73
Number of Parent Institutions	73
Number of Affiliated Institutions	178
Number of Institutions Covered	251
Range of Affiliates to Parents	
Average Number of Affiliates to Parents	2.44
Percent of Parents with One Affiliate	56%

The types of organizations that comprise the "parent" institutions are varied; included are associations, bio-tech companies, centers, clinics, institutes, foundations, hospitals, states, and university systems, to mention a few. The "affiliate's" composition is similar to the parents. The number of affiliates associated with each parent ranges from 1 to 18; the average is 2.44. More than half the parents have only one affiliate (41/73).

ANALYSIS

The first level of review was to gather certain basic data that could be used as an indicator of whether the policies for the group were feasible. The location of the affiliates in relation to the parents was reviewed, as well as whether the contact at the affiliate was the same as the parent, or different.

Table 2 - Parent and Affiliate Institutional Connections

	Same	Different	Unknown
Parent/Affiliate Geographic Location	38	31	3
Responsible Official at Parent/Affiliate	25	20	28

In slightly more than half the cases, the affiliated institution was located in the same city as the parent (38/73). This is an important consideration, as many of the parent policies included a centralized process, that is, an inquiry and investigation process conducted by officials at the parent institution, which would not be practical if the affiliate is geographically separate. The contact person for the parent and affiliate was listed as the same in 25 cases; in 20 cases a different official was designated, and in the remaining 28 cases the contact information was unknown or left blank. It is worth noting that in the nine cases, the contact person for the parent and affiliate was listed as the same person, but the affiliate(s) were located in different cities. Eight of the nine organizations were universities.

Whether or not the affiliate was part of the parent organization was not evident in most cases, with only 19 groups of affiliates being easily recognized as a part of the parent organizations, 16 groups being easily recognized as separate organizations, and 38 groups that could not be assessed. Interestingly, of the 16 parent affiliate groups that were recognized as being separate organizations, 7 listed the same individual as the responsible official for the parents as well as the affiliates.

Table 3 - Reference to Parent and/or Affiliate in Title of Institutional Policy Statement

	Yes	No
Reference to Parent	52	21
Reference to Affiliate	21	52
Reference Other Institution	5	68

The title of the institutional misconduct policy often gives some indication whether the policy is only for the parent, or includes the affiliates. Fifty-two policies of 73 identified the parent as the institution covered by the policies; the affiliate was mentioned in 21 of 73 cases, and some other organization was named in 5 other policies. (There is some overlap, as both the parent and affiliate were identified in 18 policies cases.) In addition, while the title may only mention the parent organization, a number of the policies did acknowledge some authority over affiliates.

The policies were reviewed to determine whether or not they covered the faculty and staff of the affiliated organizations. The review determined that 31 policies, or 42%, made some statement on the coverage of affiliate faculty and staff. A similar number, 28 or 38%, were silent on coverage of affiliate faculty and staff.

While the focus of the review was to determine whether the policies of the parent accounted for the existence of the affiliate, there were three instances where the affiliate had policies separate from the parent.

INSTITUTIONAL COMPLIANCE

The policies, as contained in the ORI files or provided by the parent institutions, were evaluated for compliance with the Federal regulation (42 CFR Part 50, Subpart A).

Table 4 - Institutional Compliance

	Yes
Percent of Parent Policies Compliant with Regulation	47%

Percent of Parent Policies Requiring Revision

45%

Thirty-four institutional policies were found to be in compliance, and 33 institutional policies required some revision, as a part of our review. In six cases, the policies provided were for an organization other than the parent, or there were separate policies for the parent and affiliate.

Table 5 - Affiliation Acknowledgment

	Yes	No	Undetermined
Reference to Affiliate Arrangement	13	54	6
Affiliate Acknowledges and Accepts Arrangement	8	27	38

Each policy was reviewed to determine whether there was any reference to the affiliation arrangement. This question is slightly different than a previous question that asked whether the affiliated institution was included in the policy title. Only 13 of 73 institutional policies (17%) have any reference in them to the affiliate organizations. Of that number, there was some evidence in eight policies that the affiliate organization accepted the arrangement.

CONDUCT OF THE INQUIRY AND INVESTIGATION

The policies were reviewed to determine whether the conduct of the inquiry and investigation were centralized at the parent level, decentralized at the affiliate level, or some combination of each.

Table 6 - Conduct of the Inquiry

	Parent	Affiliate	Undetermined
Inquiry Initiation Point	43	14	16
Institution Where Inquiry Conducted	40	15	18
Location of Official Responsible for Conduct of Inquiry	41	12	20
Institution Where Inquiry Conducted	40	15	18
Location of Official Responsible for Conduct of Inquiry	41	13	19
Location of Deciding Official	41	12	20

Better than half (43 of 73; 59%) of the inquiries were handled at the parent level. Only 19% (14 of 73) were handled at the affiliate level, while in the remaining 16 cases, the policies were not specific enough to make that determination. Other questions regarding the inquiry followed the same pattern: the contact person was primarily from the parent - 55% (40/73), the individual initiating the inquiry was associated with the parent in 56% of the cases (41/73), and the deciding

official was also primarily associated with the parent - 56% (41/73). Where the inquiry was held at the affiliate level, the pattern was consistent: the contact person (21%), the person initiating the inquiry (18%), and the deciding official (16%) were at the affiliate level. In approximately 25% of the cases, this information was difficult to evaluate, as the title and description of the responsible officials with a role in the inquiry and investigation were not specific enough to be positively identified with either the parent or the affiliate.

Table 7 - Conduct of Investigation

	Parent	Affiliate	Undetermined
Investigation Initiation Point	43	9	21
Location of Deciding Official	44	10	19
Location of Investigation Records	17	4	52

The pattern for the conduct of the investigation was similar to that of the inquiry. The investigation was handled at the parent level in 59% of the policies (43 of 73), and the deciding official was associated with the parent in 60% (44 of 73) of the cases. Investigation at the affiliate level were identified on only 9 of 73 policies (12%), and the deciding official at this level could only be found in 10 policies (14%). The level of the official responsible for the investigation process could not be determine in 25% of the policies.

OTHER ISSUES

The policies were reviewed to determine whether the parent institution formally distributed the policies to the affiliated institutions.

Table 8 - Distribution of Policies by Parent

Yes	9
No	1
Undetermined	63

There was evidence in the policies that this distribution occurred at only nine parent/affiliate groups. In all but one case where the policies were not distributed, the policies were silent on the issue of distribution.

Table 9 - Role of Affiliate in Naming Inquiry/Investigation Committees

Full or Complete	4
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Primary	1
None	9
Unknown	59

In only five cases (7%) did the policies acknowledge and describe a role for the affiliates in naming the inquiry and/or investigation panel. In nine cases (12%) the policies were clear that this was a responsibility at the parent level. In the majority of cases (71%), the policies were simply not clear on this topic. It is also likely that the high percentage of institutions that handle both the inquiry and investigation at the parent level (approximately 60%) simply have not made any accommodation for the affiliate, and more likely, were not designed as a multi-institutional procedure.

The review could only identify eight instances (11%) in which officials from the affiliate institutions had membership on either the inquiry or investigation committees.

A question was asked regarding who handled appeals, and the policies for the most part did not identify the official specifically enough to determine whether they were from the parent or affiliate. However, the question did yield more relevant information regarding the existence of an appeals process within the institutional policies. In only nine cases (12%) were there any provisions for an appeal.

COMPLAINANT AND RESPONDENT PROTECTION

The review of the policies also disclosed that only 31 of 73 (42%) of institutions had any reference to the protection of whistleblowers, and only a slightly larger number (37 of 73 - 51%) of the institutions identified any official as responsible for restoring the reputation of the respondent. These percentages are not inconsistent with the results of other policy reviews.

CONCLUSION

There is little evidence that any institutional policies were modified to account for the existence of the parent/affiliate relationship with ORI. For institutions that did have multi-institutional policies, they were likely developed because of the institutional relationships that existed irrespective of any interaction with ORI. For example, some universities have policies that cover several campuses; health department policies often include regional facilities. When institutions established an affiliation for the purpose of reporting to ORI, very few, if any, modified their policies to reflect this arrangement.

Part of this review involved reviewing policies for compliance with the Federal regulation, and determining whether the policies of the parents (in the absence of separate affiliate policies) were

applicable to the affiliates, and whether the affiliate would formally adopt the policies of the parents. This objective, with only a few exceptions, has been accomplished. Institutions have made their policies compliant with the Federal regulation following ORI review; affiliates are covered by compliant policies, either as part of the parent's process, or with a policy of their own.

The review did highlight the type of multi-institutional policies that are effective. There are three main models. The first model involves each institution having separate policies for dealing with misconduct at that facility. The affiliation agreement is only for the purpose of reporting to ORI. The second model involves a parent policy that makes reference to the affiliated organizations, and makes accommodations for the separate organizational structures. The third model involves aspects of the first two: there is an overall policy that covers the entire multi-organizational group, with separate procedures developed by each of the affiliates to account for their separate organizational structure. In one case, the parent developed the procedure that would be effective for each affiliated unit until that affiliate developed a procedure of its own.