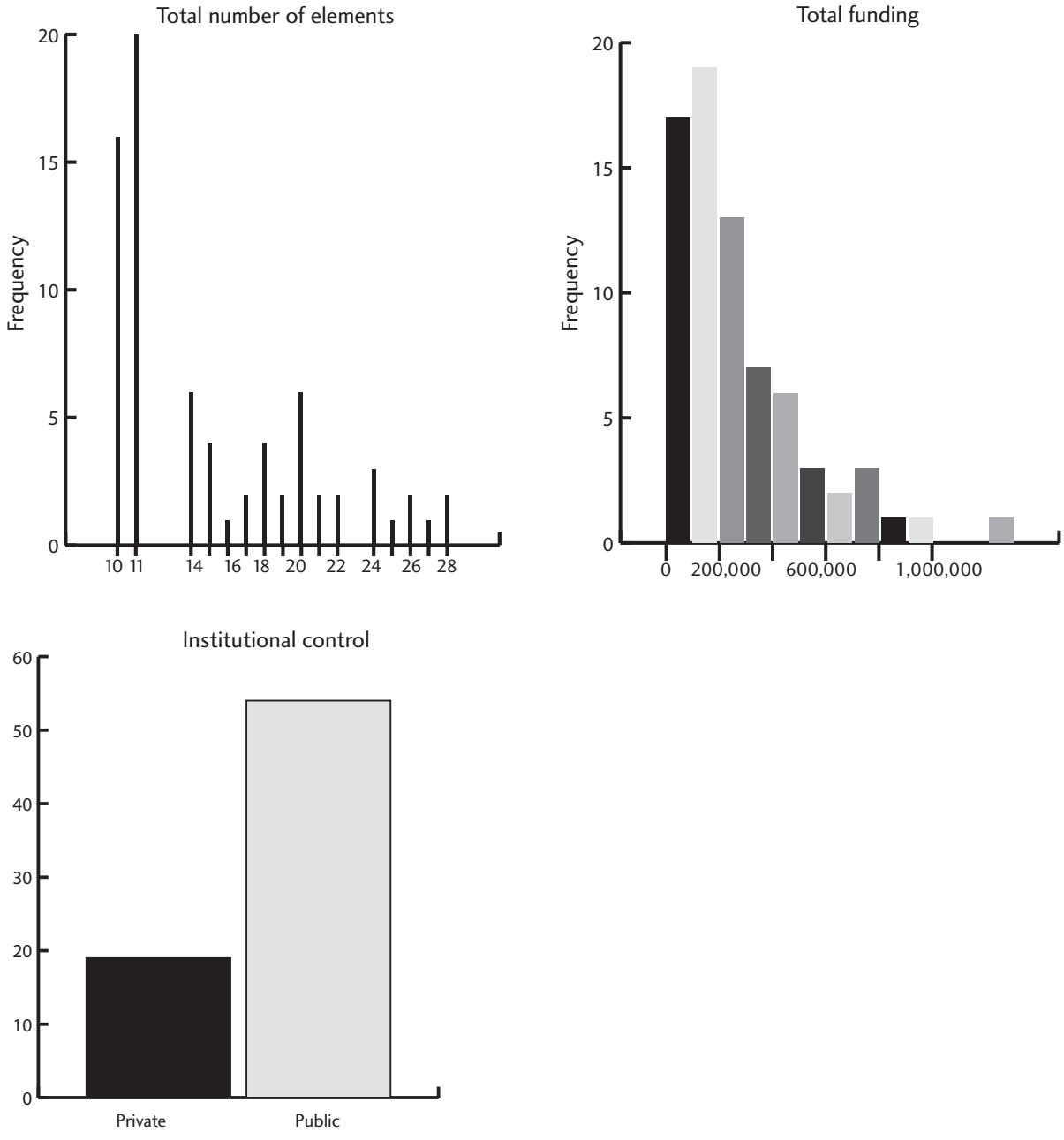
BY DAVID B. RESNIK, JULIET TAYLOR,
KATHRYN MORRIS, AND SHI MIN

A Study of Reliance Agreement Templates Used by U.S. Research Institutions

Figure 1.
Number of Elements in Reliance Agreement Templates, Total Research Funding Dollars (x 1000), and Institutional Control for 73 Academic Institutions



Appendix.
Coding Questions for Reliance Agreement Templates

Type of Template

1. Does the institution use the OHRP template or a derivative with only minor changes (such as adding the institution's name)?
2. Does the institution use SMART IRB template?
3. Does the institution use its own custom template?

Template Elements

OHRP Minimum Elements

4. Does the template include names of the institutions?
5. Does the template include names of the investigators?
6. Does the template include names of sponsors (if any)?
7. Does the template include names for projects or studies?
8. Does the template include listings for Federalwide Assurance (FWA) numbers?
9. Does the template include listing for IRB numbers?
10. Does the template include signature lines?
11. Does the template require that the relied-upon institution will comply with requirements of the FWA (i.e., compliance with ethical principles and federal regulations)?
12. Does the template require that the relied-upon institution will follow written procedures for reporting its findings and actions to the relying institution?
13. Does the template require that the relying institution will comply with its FWA?
14. Does the template require the relied-upon institution to have accreditation for its human research protection program (or equivalent)?

Additional Elements

15. Does the template address standard operating procedures for review and oversight of research with human subjects?
16. Does the template address local context issues, such as local laws or other considerations?
17. Does the template address reporting noncompliance, unanticipated problems, adverse events, or injuries?
18. Does the template address communications with regulatory agencies?
19. Does the template address audits or investigations?
20. Does the template address monitoring, quality assurance, or quality improvement?
21. Does the template address conflicts of interest?
22. Does the template address confidentiality?
23. Does the template address compliance with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA)?
24. Does the template address education in human research protections?
25. Does the template address dispute resolution or mediation?
26. Does the template address governing law for the agreement?
27. Does the template address breach of the agreement?
28. Does the template address termination or length of the agreement?
29. Does the template address scope of the agreement?
30. Does the template address severability of parts of the agreement?
31. Does the template address indemnification?
32. Does the template address insurance for human research liability?

Special Requirements to Reduce Legal Liability

33. Does the template require the relied-upon institution to have accreditation?
34. Does the template require the relying institution to have accreditation?
35. Does the template require the relied-upon institution to indemnify the relying institution?
36. Does the template require the relying institution to indemnify the relied-upon institution?
37. Does the template require the relied-upon institution to carry liability insurance?
38. Does the template require the relying institution to carry liability insurance?