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Biotechnology Research of Recombinant or Synthetic Nucleic Acid Molecules: Raising the Stakes for Governance

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Abstract

Recombinant or synthetic nucleic acid molecules are used in biotechnology research involving disease, drug discovery, and clinical applications at various facilities. The prospects and risks associated with biotechnology are monitored by Institutional Biosafety Committee (IBC). However, IBC's oversight policies have not always evolved as fast as the science leading to a decline in public trust.

This study is the first to assess the level of oversight on IBCs by examining their level of community participation. Community participation and oversight on IBCs is worthy of attention for two key reasons: 1) rapid advances in biotechnology research pose potential public health and safety effects at community, state and federal levels; and 2) individual research facilities are increasingly affiliating with systems leading to changes in the composition of IBCs.

By systematically examining IBCs in the biotechnology hub of Massachusetts, the intent of this research is to assess whether and how organizational and market changes influence the level of community participation and oversight by IBCs. The biotechnology hub of Massachusetts provides a complex landscape from which to examine the governance of biotechnology research by IBCs. These results re: IBCs raise the stakes in terms of the public's interest in biotechnology research and its governance.

Keywords: Biotechnology Research; Board Composition; Governance

Introduction

Institutional Biosafety Committees (IBCs)

The ever-increasing capability of scientists to manipulate biological systems at the molecular level pose oversight challenges to protect both the public and the environment regarding the prospects and risks of advances in biotechnology research [1,2]. Research projects involving recombinant or synthetic nucleic acid molecules at a facility that receives National Institutes of Health (NIH) funding for conducting or sponsoring such research must follow the NIH Guidelines. However, biotechnology is a growth industry that increasingly carries out research with and without NIH funding in various organizations including hospitals, small start-up companies and universities.

Given this patchwork of research facilities, gaps in monitoring the progress and risks of biotechnology research led some American towns and cities, especially in Massachusetts, to enact local ordinances. These local ordinances help address potential risks of this research for all facilities within their jurisdiction no matter the funding source. Local facility biosafety advisory boards aka Institutional Biosafety Committees (IBCs) are required by NIH Guidelines and local ordinances to review research involving recombinant DNA and synthetic nucleic acid molecules. IBCs that are registered with the NIH are responsible for reviewing research for facilities that receive NIH funding to guide its compliance with the NIH Guidelines. This study focuses on NIH registered IBCs. They are responsible for making decisions regarding the benefits and risks associated with NIH funded biotechnology research

activities conducted at the facility level.

IBCs are entrusted with decision-making at the facility level that includes public health considerations and environmental concerns such as containment strategies and managing adverse events [3]. According to NIH's Director of Outreach and Education Office of Biotechnology, IBCs "are the cornerstone of institutional systems of oversight of recombinant DNA research" [4] and serve as the interface for other "committees that review the science, safety, and ethics of experimentation from bench, through animal models, to the clinic" [4].

Community Oversight as Science Advances

Community members are included on IBCs specifically to represent public health and safety interests in recombinant or synthetic nucleic acid molecular research. Previous studies conducted decades ago found that IBC community members were often scientists who were reported as lacking the qualifications to represent the community interests with regard to the specific research concerned [5-7]. Today, the potential for underrepresentation of the community's interests is heightened given additional concerns for misuse associated with current advances in recombinant DNA techniques.

NIH Funded Research

The best safety practices for working with recombinant or synthetic nucleic acid molecules are specified in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules [3]. All projects involving recombinant or synthetic nucleic acid molecules at a facility that receives National Institutes of Health (NIH) funding for conducting or sponsoring such research must follow the NIH Guidelines. In addition, compliance with the NIH Guidelines is often a condition of receiving funding from other federal agencies or other research funding entities [8]. Therefore, all NIH registered IBCs must follow the NIH Guidelines. The NIH Guidelines were first issued in 1976 and have been updated several times since then [3]. The scope of oversight covered by the NIH Guidelines includes the formation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules. Just over 800 facilities conduct research involving recombinant or synthetic nucleic acid molecules and receive NIH funding [9]. Most of the facilities conducting this research are clustered in areas with academic research laboratories, clinical facilities, and start-up biotechnology companies [10].

Local Ordinances

At the same time that the NIH Guidelines evolved, some communities with recombinant DNA laboratories within their jurisdictions conducted public meetings with a variety of stakeholders to discuss the risks and oversight of recombinant DNA experiments [11]. In 1977 Cambridge, Massachusetts became the first city to regulate recombinant DNA with a public health ordinance that includes a mechanism for community member participation [12]. Since then, several jurisdictions in the Commonwealth of Massachusetts, including Boston, have enacted local laws re: recombinant or synthetic nucleic acid molecules largely modeled on the Cambridge ordinance [10].

These local communities, especially in Massachusetts, have embraced local ordinances as a competitive advantage and used them to draw biotechnology facilities to cities and towns [10]. The Cambridge effort to regulate biotechnology facilities was criticized by some as an impediment to scientific freedom and a barrier to attracting commercial biotechnology [10]. However, Feldman & Lowe [10] indicate these reservations have proven to be unfounded as the consensus-building within the Cambridge community has created a thriving biotechnology-business-friendly area with active community involvement and industry support. Massachusetts has actively supported the adoption of local public health ordinances to regulate recombinant or synthetic nucleic acid molecules; however, Massachusetts has not been successful in enacting a similar law statewide therefore the system of IBC oversight does not cover all biotechnology research across the commonwealth.

Community Participation: A Key Governance Mechanism for IBCs

As these areas of biotechnology continue to progress, the community-and scientists themselves-continue to raise concerns about the risks and benefits of applying the same recombinant DNA regulatory framework to these next-generation recombinant or synthetic nucleic acid molecular technologies during the research phase. In part to address these concerns, community members are selected to serve on IBCs specifically to provide community/public oversight.

Similar to boards of directors, these advisory boards (IBCs) are responsible for IBC's strategy, leadership, and stewardship of resources that pose potential benefits and risks to communities and the general public. It is reasoned that the role of community member participation makes the IBC more independent from insiders or management and thus better able to assess the effects of decisions on the health and safety of the community.

Two key points underscore the importance of examining the extent of community member participation on these IBCs. First, NIH guidelines re: community member participation changed from stipulating the proportion to specifying the number of community members serving on NIH registered IBCs. Second, research facilities underwent organizational changes that have increased their size and the proportion of insiders serving on IBCs. Consequently, as the size of IBCs grow, number of community members as stipulated by the NIH guideline tended to become

diluted raising the question of whether there is adequate community member participation on IBCs.

In addition to the level of community participation on IBCs, little is known about the background of those community members who do serve on IBCs despite community participation requirements stipulated in the *NIH* Guidelines and local ordinances. For IBCs receiving NIH funds, there are NIH Guidelines that specify the number of advisory board members (5), as well as the number of community members (2) serving on the IBC that are not affiliated with the facility [3]. The NIH Guidelines merely suggest several preferred occupations for IBC community members. These are not required. However, the background of community members serving on IBCs deserves examination given the scientific complexities together with health and economic trade-offs associated with biotechnology research.

This study is the first to examine the composition of IBCs to understand the extent of governance in the biotechnology research industry. Specifically, this examination of community participation on NIH registered IBCs in Massachusetts will assess the extent that IBCs are opening their advisory boards to the input and oversight of community members.

Conceptual Framework and Research Question

Because IBCs provide the primary mode of community participation in early stage biotechnology research, a systematic examination of the level of oversight provided by IBCs is relevant and appropriate. Given NIH guidelines and local ordinance requirements related to community member participation, this research goes beyond assessing compliance with these regulations to examine the extent of oversight by community members in relation to selected key external factors: organizational structure and local ordinances.

Drawing upon agency theory, this study focuses on the level of community member participation on IBCs as a key mechanism for oversight and monitoring of biotechnology research advisory boards. Community participation on IBCs is viewed as providing independent oversight to help ensure that biotechnology research considers the health and safety of the community in its decisions and policies. The rationale for the participation of community members on IBCs is to provide increased scrutiny and oversight thus opening the governance of biotechnology research beyond those (insiders) who actually conduct and manage research activities to include key stakeholders (community members) affected by the research.

This examination of community member board participation reflects a view of governance that involves decisions and policies that extend beyond finance, to include the health and quality of the environment and society. The oversight role of community members while consistent with corporate agency theory (monitor governance decisions and policies decision-making by insider board members) is increasingly more important given the potential risks and benefits to the health and safety of residents and the environment associated with biotechnology research decisions and facility level policies made by IBCs. This examination of IBCs provides information related to their stewardship of resources and research that have far-reaching effects on communities and the environment [13]. This governance perspective of community participation is consistent with newer thinking and frameworks that reflect broader and more inclusive interpretations of governance [13].

This study intends to answer the research question of whether IBCs have a minimum level of community participation to ensure that the governance of biotechnology research is inclusive of the independent input and oversight of community members. Additionally, it will also examine key organizational and market factors that may be influencing the level of community participation on IBCs. This preliminary study intends to add to the body of knowledge related to the level of community participation and oversight to assess the level of openness and inclusion involved in the governance of biotechnology research.

Methods and Data Sources

Study Population

The Commonwealth of Massachusetts was selected because it has a disproportionately high number of biotechnology research facilities as compared to the rest of the U.S. and therefore is considered an active biotechnology hub worthy of examination. Massachusetts is the leading life sciences research and development state, employing nearly 30,000 people in this field [14]. A total of 48 out of 800 NIH registered IBCs are located in Massachusetts. NIH registered IBCs are responsible for reviewing cutting edge biotechnology research. Massachusetts also has a growing number of research facilities that are part of a (affiliated) system thereby offering an opportunity to examine this emerging organizational trend in the study population of NIH registered IBCs in Massachusetts. The role this biotechnology hub played in sparking public involvement in recombinant DNA research [11] coupled with the early adoption of local biosafety ordinances to oversee compliance of this research further strengthens the rationale for selecting this location for this study.

This is formative research for several reasons: 1) there is no public information available re: IBCs and their advisory board members, 2) even though the NIH requires community board member participation on IBCs that receive NIH funding, these data have not been systematically collected. The unit of analysis in this study is the NIH registered IBCs in Massachusetts. This study population consists of the 48 IBCs serving the 48 non-governmental facilities that are located in Massachusetts that have registered with the NIH.

Data Sources

A facility with an NIH registered IBC is required to submit an IBC roster annually to the NIH Office of Biotechnology Activities (OBA) [3]. Since NIH registered IBCs are mandated to report compositional and other related data annually in the IBC roster, this data requirement helped define the study population. Data about all 48 non-governmental facilities located in Massachusetts with NIH- registered IBCs were primarily collected from the most recent IBC rosters reported by IBC administrators to the NIH (OBA). Data were also obtained from an IBC facility list provided by the NIH OBA and Cambridge Public Health Department. Additional data about local ordinances and limited community member information were obtained from other sources not affiliated with the NIH. The fiscal year 2012 was used because the most current rosters provided by the NIH OBA were also from 2012, and the data were frozen at the end of each fiscal year.

Outcome Variable

The outcome variable is community member participation on IBCs. For IBCs receiving NIH funds, there are NIH Guidelines that specify the total number of advisory board members (5), as well as the number of community members (2) serving on the IBC [3]. NIH registered IBCs are permitted to have more IBC members than 5 and thus the size of IBC has grown. This is noteworthy as the influence of outside community members can be diluted by larger IBCs as there is no restriction on the number of insider IBC members.

Local ordinances have similar IBC compositional requirements that stipulate the number (i.e. 2 or 3) of community members. The NIH Guidelines formerly required that at least 20% of IBC be comprised of community members [5]. This study will examine the size of the IBC as well as the percentage of community member participation on the IBC. Guidance from previous NIH Guidelines that specified minimum of 20% has been applied as the operational definition of minimum community participation for this study.

Predictor Variables

Expertise of community member

Community members' ability to understand the complexities of biotechnology research and have a voice in the governance of facilities in their participation on IBCs are usually based on their expertise. Proxies for expertise can be problematic. While community members are thought to represent and safeguard the interests of the community, the scientific scope required to participate on IBCs can be beyond that of most citizens and thus limit community member participation. Alternatively, a person's scientific expertise can be co-opted by the facility's other interests as it can lead to biased support of biotechnology research despite potential risks to the community. Granted these somewhat conflicting effects of scientific expertise in terms of helping and impeding IBCs make decisions in the communities' best interests, nonetheless, this community member characteristic will be examined. This study will assess the expertise of community members by identifying their terminal degrees (i.e., Ph.D., M.D., D.V.M.) as these are considered a validation of knowledge required for technocratic decision-making such as IBCs [15].

Organizational characteristics

An emerging organizational type identified in this study is the formation of system-wide IBCs. This system affiliation occurs when two or more facilities operate their IBCs jointly under one administrative function. This type of structure helps lower costs for each member facility by spreading administrative overhead associated with using the IBC to oversee compliance across more facilities. The system-wide IBCs must file their IBC roster with NIH OBA separately even though they function on a multi-facility level. As health facilities and other organizations continue to restructure and reorganize into larger systems and entities [16], the governance of these entities become more complex [17].

Facilities that are of the same ownership type are likely to have similar reactions to external factors, according to DiMaggio & Powell [18]. Organizational types and structures are likely to affect the way organizations respond to external expectations in the context of governance. The NIH relies on both for profit and not-for- profit organizations in conjunction with governmental research laboratories to meet research goals based on public value. Earlier studies indicate that ownership influences board composition especially for hospitals [19,20]. In this study system affiliation and ownership will be examined among the NIH registered IBCs in Massachusetts.

Market characteristic

Massachusetts uniquely has several municipalities with local ordinances. It has been argued that local ordinances provide stability to the biotechnology industry [10]. Yet the effect of local ordinances on the composition of NIH registered IBCs is unknown.

IBC community members in municipalities with local ordinances must meet the criteria of the local regulations. In this situation, the Public Health Commission often has control over community member appointments to IBCs. This control is implemented differently in various municipalities, which may exercise appointment powers, the authority to approve the appointments, or-in some cases-community member training requirements. Some ordinances require a board of health agent or his or her designee to be on the IBC. In Massachusetts, local ordinances greatly increase the number of facilities required to meet oversight regulations for research involving recombinant or

synthetic nucleic acid molecules [12]. Without local ordinances, many facilities would not be regulated with respect to recombinant or synthetic nucleic acid molecules, as no federal or state level laws regulating research involving recombinant DNA or synthetic nucleic acid molecules exist. Given the importance of local ordinances especially in Massachusetts, the presence of local ordinances will be examined.

Data Analysis Plan

This formative examination is not a confirmatory analysis of a specific research hypothesis rather it makes observations about IBCs in the study population to guide practitioners and future research. Given that the IBC is the unit of analysis and the number of NIH registered IBCs operating in Massachusetts in 2012 was 48, the purpose of the analysis was to assess whether and how a few key factors like system affiliation and, ownership coupled with the presence of local ordinances were influencing community participation on IBCs.

The descriptive statistics for each of the study variables provide a profile of NIH registered IBCs in Massachusetts (Table 1). Descriptive statistics summarized the data and provided an opportunity to assess the distributional features for each variable including frequency and percentage. NIH registered IBCs in Massachusetts are profiled (univariate analysis) by their composition and characteristic attributes (community member participation, education/scientific expertise of outsider members), and the structural profile (system affiliation and facility ownership type) and market/local area characteristics (presence of local ordinances). Bivariate analysis included a contingency table to compare the outcome variable with each predictor variable to identify the frequencies in each cell.

A correlation matrix (Table 2) was used to examine associations and relationships between and among these study variables to assess cell frequencies and multicollinearity. Multivariate (binary logistic regression) is used to assess selected predictors associated with the outcome variable, community member participation.

Before the data were analyzed, values for each variable were entered into the Statistical Package for the Social Sciences (SPSS), Version 20.0 [21]. Each value was reviewed for consistency and potential missing data. There was no missing information, so all the values were complete for the data set. Once distributions for study variables were examined for normalcy, the variables were operationalized as dichotomous. For all procedures that involve significance testing, the result is considered statistically significant if the p-value is less than .05.

Results

Univariate Analysis

A profile of the NIH registered IBCs in Massachusetts is detailed in descriptive statistics for study variables shown in Table 1. The vast majority of the facilities 36 (75%) governed by IBCs were not for profit. Most of the IBCs 35 (73%) represented stand-alone facilities vs. those with a systems affiliation. A majority of facilities with NIH registered IBCs 30 (62%) were located in municipalities with local oversight ordinances. Almost a third 15 (31%) of IBCs reported that had at least half of their community members had a doctorate degree showing a high level of science expertise and 33 (69%) had less than 50% of their membership with a doctorate degree. Over half 28 (58%) of the IBCs reported community participation at or exceeding 20% of their board membership. A closer look shows that voting membership on IBCs ranges from 5-22 members including 1-3 community members.

Variable	Description	Freq uency	Perce ntage
IBC Composition Community Member Participation	Outsiders < 20%	20	41.67
(ranges from 5–22 voting members)	Outsiders ≥20%	28	58.33
	Total	48	100
Scientific doctorate degrees of community members	Has doctorate < 50%	33	68.75
	Has doctorate ≥50%	15	31.25
	Total	48	100
Ownership Type	For-profit	12	25
	Not-for-profit	36	75
	Total	48	100
System Affiliation	Stand-alone IBC	35	72.92
	System-wide IBC	13	27.08
	Total	48	100
Local ordinance	No local ordinance	18	37.5
	Local ordinance	30	62.5
	Total	48	100

Table 1: Study Measures and Descriptive Statistics - NIH registered IBCs 2012 Massachusetts Non-Governmental Facilities (n=48).

Bivariate Results

The result of Pearson's correlation as shown in Table 2 provides evidence for the construction of the binary logistical regression model. Because IBCs with at least 50% of the outside members with doctorate degrees indicating science expertise was significantly correlated with other predictors, it was excluded from the binary logistic regression model. There were no significant correlations between and among any of the predictors: system affiliation, ownership, local ordinance. There were correlations between predictors and community participation.

Variables	1	2	3	4	5
1. Ownership type	1	-0.2	-0.2	.44[a]	.29[a]
2. System Affiliation	-0.24	1	0.09	-.31[a]	-.44[a]
3. Ordinance	-0.15	0.09	1	-.41[a]	-.39[a]
4. Scientific Expertise	.44[a]	-.31[a]	-.41[a]	1	.30[a]
5. IBC community participation	.29[a]	-.44[a]	-.39[a]	.30[a]	1
[a] Correlation is significant at the .05 level (2-tailed)					

Table 2: Correlation of Variables with IBC Composition (n=48).

Multivariate Results

The binary logistic regression results (Table 3) for IBCs that have at least 20% community member participation on their advisory boards indicate that stand-alone IBCs were 9.7 times more likely to have this increased level of community member participation as compared to system affiliated IBCs. In addition, IBCs located in municipalities without a local ordinance were 8.3 times more likely to have 20% or more community members serving on their IBCs. The logistic regression results indicate that both system-wide IBCs as a structure that combines the members of more than one IBC in practice yet registers the IBCs separately and local oversight ordinances that provide and additional layer of oversight have a negative influence on the IBC's community member participation. Ownership type was not a contributing predictor to community member participation.

	Community member participation ≥ 20% outsiders on NIH registered IBC (n=48)
Independent Variables	**Odds Ratio (95% CI[a]) P**
Facility ownership type (not-for-profit vs for profit)	2.83 (0.48-16.90) >.253
IBC System Affiliation (system-wide vs stand alone)	9.71 (1.57-60.21) <.015 [b]
Local ordinance oversight (located in area with ordinance vs area with no ordinance)	8.31 (1.47-47.14) <.017 [b]
[a]CI= confidence interval, [b]Significant at < .05	

Table 3: Binary Logistical Regression Results for Community Member Participation on IBCs (n=48).

Discussion

As research organizations, hospitals, educational institutions and for-profits grow and re-structure to remain viable in this increasingly competitive biotechnology industry, they are looking for opportunities to become more efficient. System-wide IBCs by their nature are one such mechanism that can improve efficiency while increasing consistency in decision-making across the system members.

A key finding is that IBCs from system affiliated facilities are significantly less likely to have a minimum level (20%) of community member participation on the IBC. To better understand the significantly lower level of community participation on these system affiliated IBCs, some background information can provide useful context and insight.

It is not surprising that these system facilities require more inside members to ensure representation from all affiliated facilities. This would increase the size of IBC thereby diluting the proportion of community member serving on these IBCs. A review of research projects in NIH RePORTer [22] shows system facilities typically conduct a greater diversity of research than stand- alone facilities. This tends to increase the complexity of IBC decision-making and this is addressed by having more insider members on the IBCs. Furthermore, a careful review of the IBC rosters has shown that

system-wide IBCS often share community members thereby reducing the number as well as proportion of different community members. This is likely due to the difficulty in recruiting, training and retaining community members that could influence this shared community member resource. These practices do raise the stakes in terms of having governance mechanisms that provide oversight to protect broader public interests of health and safety. More research is needed to determine the effects that less community participation on IBCs may have related to the performance of these facilities.

This study also found that local ordinances are significantly associated with less community member participation in NIH registered IBCs. Local oversight greatly increased the number of facilities required to meet oversight regulations for research involving recombinant or synthetic nucleic acid molecules [12]. For example, the city of Cambridge has a local ordinance that applies to nearly 100 facilities engaged in research involving recombinant or synthetic nucleic acid molecules while the NIH requires oversight at only 7 of these facilities because of funding [12]. On the surface, it seems the benefits of the local oversight ordinances are in the best interests of the industry and the public. Regulatory capture theory cautions us to not just assume public good rather "is regulation simply an arena in which special interests contend for the right to use government power for narrow advantage?" [23]. Perhaps more effective oversight mechanisms are included in the ordinances thus lessening the need for more community member participation. One way to know less community member participation reflects less inclusive governance is for additional research that examines whether the performance of these IBCs with local ordinances is better or worse than those without ordinances.

Limitations and Future Research

The study population of NIH registered IBCs is a limitation because it was small and unique. Granted that Massachusetts has non NIH registered IBCs involved with biotechnology research, the NIH registered IBCs are the most active in terms of reviewing cutting edge research. Additionally, NIH registered IBCs are primarily the only IBCs operating in other states in the US since local ordinances are largely in Massachusetts. Thus while the study population may have limited generalizability for Massachusetts, it may have broader generalizability for IBCs in other states.

Other points to note are Massachusetts' early adoption of local ordinances and it's growing number of system-wide IBCs. These make Massachusetts a distinctive market and landscape that may not be generalized to other states. Nonetheless, this examination of Massachusetts provides a complex landscape that reflects organizational and market changes that can provide a lens to view trending in other biotechnology hubs across the country. Future research with a larger sample population could help validate associations of governance variables described in this study.

Conclusion

For these reasons, the IBC is the most obvious starting point that can improve the oversight decision-making processes for biotechnology research that has raised the stakes for governance. These compositional findings about IBCs have raised the stakes for governance. Because biotechnology is advancing rapidly and IBCs play a prominent role, the timing of this study is important to draw attention to examining whether the oversight system established long ago for transparency and accountability in lieu of federal regulations is providing the open and inclusive governance needed to protect the health and safety of communities and their citizenry. This preliminary examination of the governance in biotechnology research is but a first step to guide future investigation and analysis.

References

1. Fogleman VM (1987) Regulating science: An evaluation of the regulation of biotechnology research. Environmental Law 17: 183.
2. Patterson AP, Tabak LA, Fauci AS, Collins FS, Howard S (2013) A framework for decisions about research with HPAI H5N1 viruses. Science, 339: 1036.
3. NIH Guidelines 2013. "NIH guidelines." office of science policy - national institutes of health office of biotechnology activities.
4. Shipp A (2003) Guest article: IBCs, IRBs, and IACUCS: Creating a stronger foundation for the oversight of recombinant DNA research. ARENA Newsletter,Winter : 4-5.
5. Bereano PL (1984) Institutional biosafety committees and the inadequacies of risk regulation. Science, Technology, & Human Values, 9: 16-34.
6. Dutton DB, Hochheimer JL (1982) Institutional biosafety committees and public participation: Assessing an experiment. Nature, 297: 11
7. Jaggar SF, Nadel M, Carroll D, Featherston F (1987) Briefing report to the chairman, committee on science, space and technology, house of representatives biotechnology role of institutional biosafety committees Washington, D.C.: United States General Accounting Office.
8. "NIH guidelines FAQs." national institutes of health office of biotechnology activities. april 2013.
9. Jambou R (2013) FOI case no. 40967 interim response. personal correspondence, bethesda: Department of health and human services.
10. Feldman M, Lowe N (2008) Consensus from controversy: Cambridge's biosafety ordinance and the anchoring of the biotech industry. European Planning Studies, 16: 395.
11. Krimsky S, Ozonoff D (1979) Recombinant DNA research: The scope and limits of regulation. American Journal of Public Health 69: 1252-1259.
12. Lipson S (2013) (Director of environmental health, cambridge public health department).
13. Tihanyi L, Graffin S, George G (2014) Rethinking governance in management research. Academy of Management Journal, 57: 1535-1543.

14. Mass Bio BioReady communities. 2013.

15. Fischer F (2009) Democracy and expertise: Reorienting policy inquiry. New York, NY: Oxford University Press.

16. The Governance Institute (2011) 2011 Hospital and Health System Governance Survey.

17. Alexander JA, Weiner BJ, Bogue RJ (2001) Changes in the structure, composition, and activity of hospital governing boards, 1989-1997: Evidence from two national surveys. Milbank Quarterly 79: 253.

18. DiMaggio PJ, Powell WW (1983) The iron cage revisited: Institutional isomorphism and collective rationality in organizational fields. American Sociological Review: 147-160.

19. Molinari C, Morlock L, Alexander J, Lyles CA (1993) Hospital board effectiveness: Relationship between governing board composition and hospital financial viability. Health Services Research 28: 358-371.

20. Brickley J, Van Horn R, Wedig G (2010) Board composition and non-profit conduct: Evidence from hospitals. Journal of Economic Behavior & Organization 76: 196-208.

21. IBM Corporation. 2011. IBM SPSS statistics for windows, version 20.0. armonk: IBM corp.

22. NIH research portfolio online reporting tools (RePORTER).

23. Levine ME, Forrence JL (1990) Regulatory capture, public interest, and the public agenda: Toward a synthesis. Journal of Law, Economics, & Organization 6: 167-198.