BIOMEDICAL RESEARCH ADVISORY GROUP:
ORGANIZATIONAL STRUCTURES SUBCOMMITTEE REPORT

1. EXECUTIVE SUMMARY

Harvard University is a complex institution, composed of extraordinary resources and outstanding programs. Harvard's structural complexity is particularly evident within the HMS community, which alone is comprised of Quadrangle departments, 14 separate 501(c)3 multidisciplinary healthcare centers, a number of biomedical research organizations, and the Harvard School of Dental Medicine. In addition the Harvard School of Public Health is located in the Longwood Medical area and a member of this biomedical community. While each of these institutions contributes richly to the HMS, geographical locations, distinct cultures, widely disparate resources, and keen self-identities pose considerable challenges for collaborative research, education, and for a strong sense of community at HMS. When viewed from the outside, the Harvard biomedical community is often characterized as internally competitive and failing to achieve synergy that would add to be more than the sum of its parts. To develop strategies to more fully achieve our potential, the Biomedical Research Advisory Group convened a subcommittee to consider whether new organizational structures could be created across the broad HMS community so as to capitalize and advance current strengths, while simultaneously building new pathways to enhance communication and collaboration. Importantly, the only desired outcome from these new organizational structures was greater integration of diverse programs throughout the HMS community that would take advantage of combined excellence, build synergies across programs and institutions, avoid duplications, and maximize the scientific and educational potential at HMS. While the subcommittee recognized considerable opportunity to envision structures that included the broader University community, the focus of these deliberations was HMS.

A unique feature of the HMS community, and possibly its greatest organizational challenge, is its large number of non-quadrangle based institutions. Currently, approximately 90% of the faculty and 80% of biomedical research funding are located outside of the traditional boundaries of HMS, the quadrangle. In addition to research, non-quadrangle based faculty have assumed substantial responsibility for teaching medical students both in their preclinical and their clinical years, and for training graduate students and many post-doctoral research fellows in basic research and translational science. These two elements, biomedical research and education provide a common ground on which the HMS community could unite to develop interdisciplinary approaches that advance fundamental scientific knowledge that impact on medicine and related societal and global issues. To achieve greater excellence in these arenas the subcommittee sought new strategies to promote communication, collaboration and integration across the entire HMS community.

The subcommittee first considered the nature of the "Harvard Medical Community" and identified strengths and weaknesses of its current organizational structures. The

subcommittee then focused on challenges to the development of cross-institutional structures and defined approaches to enable intellectual community by removing barriers, encouraging interactions and advancing shared goals, while not undermining the successful individual aspects of existing institutions. While a summary of these strategies follows, we point out 3 critical elements. First, that new organizational models are motivated by the aspirations of faculty; these are intended to be grass-roots initiatives that excite and engage faculty and students. Second, some over-arching mechanisms are needed to break down practical cross-institutional barriers (e.g., institutional IRBs, AICUC, MTAs). Third, success of these initiatives is dependent on significant investments that should come from collaborating institutions. While the subcommittee recognized considerable planning and deliberation will be needed to address intellectual, financial, geographic, and space requirements for implementation of the proposed strategies, we are also certain that the rewards from such efforts would be transforming.

2. The Impact of A Name

Growth of the non-quadrangle based HMS institutions has led to confusion as to the intended meaning of by the term Harvard Medical School. The narrow view of HMS relates this name solely to quadrangle-based activities, with other, related institutions referred to as "HMS affiliated institutions." Faculty are often similarly divided into quad-based or "pre-clinical" faculty and "HMS-affiliated faculty" or "clinical faculty". Given that many non-quad faculty who are equally distinguished in their accomplishments, who contribute significantly to both medical and graduate student education and lead robust research programs that are interchangeable with quad-based faculty, the subcommittee felt that the term "affiliate" was both inappropriate and even depreciative. To eliminate the sense of a two-tiered faculty at HMS the committee proposed that "Affiliate" be removed from the HMS lexicon. In its place, we recommend an alternative nomenclature:

"HMS Quadrangle"
"HMS Hospitals"
"HMS Institutes" (non-hospital entities)
"HMS Biomedicine"
"HU Biomedicine"

We denote the entire biomedical enterprise at HMS quadrangle, hospitals, schools (HSDM, HSPH) and institutes as "HMS Biomedicine", and when inclusive of the University as "HU Biomedicine". We have adopted these names throughout this document.

3. Strengths and Weaknesses of Traditional Department Models

We first sought to review the major existing structures of HMS Biomedicine including traditional departments as well as existing examples of cross-institutional structures.

A. HMS Quadrangle departments are the academic home of world-class scientists who are recognized as leaders in their respective fields. HMS preclinical departments have evolved, changing and expanding focus as the research in the field has evolved (e.g., both BCMP and Cell Biology were created by fusing two Departments, while the Departments of Pathology and of Microbiology and Molecular Genetics resulted from the breaking up of the Department of Bacteriology). New Departments have been created in recognition of burgeoning new fields of research (e.g., Systems Biology). The size and physical co-localization of faculty determine both the desirable features and the limitations of such structures. Department structures create an environment that is cohesive and nurturing and allow for shared resources and other efficiencies. The limitation was a sense that these create small and exclusive groups as separate silos.

B. HMS Hospital and Institute departments are the academic homes for world-class physicians, clinical scientists and fundamental researchers. The mission of clinical Departments has evolved from traditional patient care to also include a range of subspecialty fields, a broad spectrum of translational and basic science research, and education of medical and research trainees. The size and multipart mission and structure of these institutions contribute to their strengths and limitations. The structure has allowed enormous growth of the faculty that includes practicing physicians, educators with advanced subspecialty skills, and scientists whose programs may be highly translational or very basic and indistinguishable from faculty in Quadrangle Departments. While Quadrangle Departments generally have fewer than 30 faculty, clinical faculty in some departments, medicine for example, can exceed 500 per department. This size is unwieldy, and the faculty are geographically dispersed. Faculty in these departments often feel little sense of community, or cohesiveness and sometimes lack a nurturing environment. This has been balanced, in part, by the development of strong divisions within the Departments that provide a community with a shared clinical and research focus on one organ system. However, with continued expansion of hospital faculty, the sizes of most divisions exceed that Quadrangle Departments.

Hospital and Institute Departments and Divisions also produce silo effects. Basic researchers in one Department are often isolated from other researchers at the same institution. Researchers working on similar problems at different institutions are separated from one another by a number of barriers. Additionally, basic scientists in clinical Departments often cannot obtain links to graduate programs and access to talented students who are recruited to HMS in part because of the success and reputation of the entire HMS Biomedicine faculty.

C. Missed opportunities resulting from the nature of the current organizational structures. The deleterious consequences of physical, institutional and political separation of HMS Biomedicine faculty are many.. Among the most important are diminished successes in basic science, difficulties in building and achieving translational research, missed or blocked funding opportunities, reduced national competitiveness, uneven access to resources and infrastructure, and obstacles for faculty interactions at all levels. In basic science, investigators in the Hospitals and Institutes are frequently isolated from one another and from Quadrangle faculty. Collaborations in both basic and translational research among faculty are impeded by differences in regulatory and related compliance requirements (IRBs, IACUCs, MTAs, IP) because each institution has

distinct forms, requirements and committees, and each interaction is examined in isolation. Large funding opportunities are increasingly linked to inter-institutional and inter-disciplinary applications which are often more difficult to organize among the separate Harvard institutions than between Harvard and unrelated institutions. National and international recognition for individual programs is good, but it is far less than what would be possible in many areas of research if the efforts across Harvard's institutions were brought together, by creating a more cohesive, communicative and collaborative environment, or in some cases by even combining programs. These problems impact the recruitment of trainees and of faculty and may inhibit interactions with industry and philanthropy. Service cores are sometimes unnecessarily duplicated. Finally, and perhaps most importantly, for many researchers there is no sense of an overarching community in which all participate, resulting in a culture of separation rather than interactive collaboration. This has many negative effects, including reducing opportunities for comprehensive education and training programs.

4. Examples of Successful Cross-Institutional Structures

Despite all of these challenges, cross-institutional structures have emerged within HMS Biomedicine, some of which are very successful. In some cases the structure was motivated by external funding sources; in others, it resulted from the strong wish of faculty with similar interests to collaborate despite all barriers. In all cases strong leadership was key to the success of the programs.

Dana Farber/Harvard Cancer Center (DF/HCC): The DF/HCC was initiated due to the requirement that a Harvard-wide Cancer Center be formed in order to receive NIH funding. It successfully brought various groups together under a single umbrella, with a shared mission. It established a Governance Committee comprised of the CEO/Presidents/Deans of the respective institutions, a Director, Deputy Director, Executive Committee, External Advisory Board and a Center Scientific Council. It is a "virtual" research organization that owns no space.

DF/HCC research efforts are organized into 18 programs that represent either research disciplines (Biostatistics, Cancer Cell Biology, Cancer Epidemiology, Cancer Genetics, Cancer Immunology, Cancer Risk Reduction, Outcomes Research, Translational Pharmacology & Early Therapeutic Trials) or cancer disease sites (Breast Cancer, Gastrointestinal Malignancies, Gynecologic Cancer, Head and Neck Cancer, Kidney Cancer, Leukemia, Lung Cancer, Lymphoma and Myeloma, Neuro-Oncology, and Prostate Cancer). As an organizational principle, DF/HCC's goal is to stimulate research between programs and particularly to enable research initiatives between discipline and disease programs. As examples of its success, there are approximately 1000 PIs from the seven member institutions and total funds for cancer research in the DF/HCC groups have grown from $100M eight years ago to over $350M per annum now. There are 45 multi PI program project grants and 8 SPORE grants in addition to the NCI's cancer center support grant of $11M.

The Clinical and Translational Sciences Center (CTSC) was similarly motivated by the NIH requirement to bring all Hospitals and Institutions of the Harvard Community

together in order to apply for CTSC funding for patient oriented research. The CTSC has learned from DF/HCC's example, and may turn out to be successful along the same lines.

Committee For Immunology: The Committee for Immunology, in contrast, was not formed in response to an NIH mandate. It was formed as a grass roots organization of basic science faculty and translational researchers seeking an intellectual community and through the leadership of Nobel Laureate Baruj Benacerraf, who as chair of the Pathology Department proposed a separate graduate program for the immunological sciences. Recognizing the relevance of Immunology to the clinical world, he envisaged a Committee for Immunology, in which hospital-based faculty would be on an equal footing with members of the Quadrangle Pathology Department engaged primarily in basic research. This vision has held to this day. The present day Committee for Immunology has more than 90 faculty members and is a broad-based, inclusive organization with extensive participation by faculty in every HMS Hospital and Institute, the Quadrangle, as well as other HU schools including the HSPH and FAS. Examples of its success are its number one ranked graduate program and the fact that more than one quarter the US members of the Immunology Section of the National Academy of Sciences are faculty members of the program.

Harvard-MIT Broad Institute: The philanthropy of Eli and Edythe Broad led to the founding of the Harvard MIT Broad Institute in 2003. Spawned by a generous gift of $200m (over 10 years) and increased by university investments, the Broad has established an interactive structure of platforms and programs to advance discovery of the causes of human disease and new approaches to treat these. Rigorous high-throughput platforms are devoted to sample acquisition, processing, curation and storage, and for analyses using state of the art and emerging technologies in genetics and genomic sequencing, computational biology, chemical biology, RNAi, proteomics and imaging. The Broad programs provides a vibrant academic community for Broad, Harvard and MIT investigators, who are are organized along 8 disciplines: Cancer, Genome Biology and Cell Circuits, Psychiatric Disease, Metabolic Disease, Medical & Population Genetics, Chemical Biology, Infectious Disease and Computational Biology & Bioinformatics. Participants in these scientific programs come from core Broad member laboratories and associate member laboratories. There are fewer than 10 core member laboratories at the Broad with approximately 75 graduate students and post-doctoral fellows. In contrast there are more than 100 associate members engaged in Broad activities. These faculty have primary laboratories are located at MIT, HMS (quadrangle and Harvard hospitals) and HSPH. These scientific programs organize their communities through frequent (typically weekly) joint group meetings where presentations discuss new data, share ideas and launch collaborative projects. The active participation by senior level faculty from multiple institutions and lively discussions make these group meetings a terrific opportunity for trainees to interact with faculty and to learn about emerging science from a diverse and creative group of scientists. Beyond academic successes, the yield on this investment has been considerable. Today, the Broad Institute receives approximately $140M/yr. (inclusive of indirect costs) in non-philanthropic grant funding (NIH and other). The Broad also serves as a national resource for the NCI's Initiative for Chemical Genetics, a public-private RNAi Consortium, NHGRI's National Genotyping Center, and is a flagship for the International Haplotype Map Project.

5. PROPOSED GENERAL MODEL FOR THE ORGANIZATION OF CROSS-INSTITUTIONAL TEAMS: HARVARD BIOMEDICINE INITIATIVES

What can be done to encourage the emergence and success of more cross-institutional collaborative structures? The committee considered several existing cross-institutional and collaborative structures, and identified critical elements contributing to their success. These include:

1) Defined mission for the collaborative organization. The mission may be singular (e.g., the Committee on Immunology's focus on education), or multiple (e.g., the Broad Institute's technology platforms and scientific programs).

2) Faculty from multiple (HMS and/or broader) communities. We found that collaborative structures that engaged multiple faculty from at least 2 institutions had far greater effect on broader community than more limited partneships.

3) Strong leadership. This was especially important in the early development phases of successful collaborative structures. We recognized the need for champions with a clear vision of the benefits that would come from collaboration and who understood the complexities and barriers that needed to be addressed. Indeed, most of the successful cross-institutional structures were predicated on the hard work of a few leaders.

4) Effective governance. A system was needed to define rights and responsibilities associated with membership, provide oversight for cores, courses and lectures, students, and other collective efforts, and assume fiscal responsibility. Governance was often organized through an executive committee that was inclusive of participating communities and that set goals and priorities.

5) Financial support. Resources were essential for the development of an infrastructure that fostered communication, education, and administration of cores, for acquisition of core technologies and specialized staff scientists, and sometimes provided funds to motivate inter-community collaborations. While unfunded collaborations sometimes succeed, (e.g., the Committee on Immunology) financial support accelerates collaborations, enables broader reaches and greater risks. As a consequence, solid financial support invigorates a culture of collaboration.

6) Teaching. Remarkably, education was a key component of all successful collaborative structures, even those organized around unrelated missions, such as technology. Teaching occurred through formal graduate programs (e.g. Immunology, Chemical Biology, Systems Biology), through regular, community-wide seminars (e.g., Immunology, Broad) or with the development of Nano courses and seminar programs developed around specific technologies.

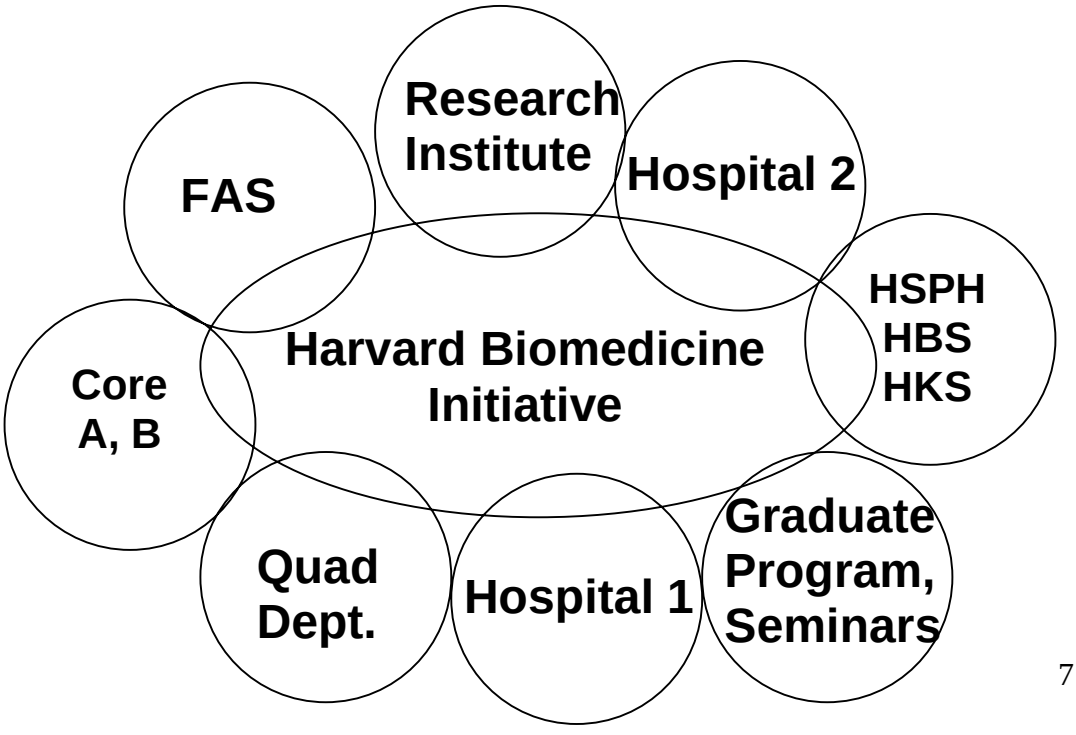
Other elements varied among the organizations we considered. 1) Physical space that provided a convening place for the community and for teaching was highly valued but recognized as not essential for success. 2) Appointing power was generally not essential for successful organizations. The lack of appointing powers was recognized as a concealed benefit: by avoiding the creation of a silo, this lack creates the conditions for recruitment of a broad, diverse faculty, which in turn allows flexibility of membership and fosters nimbleness in accomplishing goals. However, most of the successful

organizations recognized the importance of partnering with departments to recruit new faculty and promote a sense of community. 3) Membership was structured in various ways. Most had a tiered membership, with a small number of faculty with leadership roles, and expanded circles that encompassed more individuals with less direct or consistent involvement in the community.

Based on these observations, the committee proposed a general model for the creation of new inter-institutional organizations among the broad HMS community. We denote these as Harvard Biomedicine Initiatives. We expect that Initiatives will emerge from ideas and goals put forward by faculty that bring together communities across HMS and/or other Harvard schools to address a shared mission and/or to promote research and education. Harvard Biomedicine Initiatives would be supported to define and develop enabling cores and to teach. We expect that the mission of an Initiative might focus on a scientific discipline (e.g., microbial sciences), a tractable biomedical issue (e.g., novel therapeutics for drug-resistant TB), an emerging technology (e.g., personalized genotyping) or a novel educational strategy (e.g., integrative training of MD and PhD students). Based on scope, membership in an Initiative could be quite diverse (including faculty from HMS, hospitals, other Harvard schools and related institutions) and tiered. The need for physical space would also vary. However, Harvard Biomedicine Initiatives would share the following common features:

1. They are grass root organizations, composed of faculty from at least 3 communities who are united in a shared mission.
2. They have a strong leadership and a defined governance structure
3. They organize teaching in some form
4. They receive support for key personnel, infrastructure, information technology and cores.

Harvard Biomedicine Initiatives organize faculty around an educational initiative, a scientific program, or a technology initiative in a flexible structure (see diagram).



A Harvard Biomedicine Initiative might focus, for example, on emerging drug-resistant pathogens. Faculty might involve investigators from the Quad Departments of Microbiology and Molecular Genetics, and Biological Chemistry and Molecular Pharmacology, from the Hospital-based clinical and basic faculty from Infectious Disease and Immunologic Divisions, from the Broad Institute Infectious Disease Program, and from the Harvard School of Public Health. Initiative-supported cores might include a human pathogen repository and a microbial genome sequencing facility.

A second Harvard Biomedicine Initiative might focus on development of technologies that enable high-throughput personalized genotyping. Faculty might include technology-oriented members of the Quad Department of Genetics, of the School of Engineering and Applied Sciences, or of the Broad Institute, together with clinical faculty who apply personalized genotyping to disease manifestations or treatment response, and Kennedy and Law Schools faculty who study the impact of predictive genotypes on healthcare law and public policy. Initiative-supported cores might include a low-cost medical sequencing facility.

Faculty leaders of these Harvard Biomedicine Initiatives would formalize roles and responsibilities for membership, assess and develop needed cores, and provide strategies to promote collaborative interactions and teaching. A governance structure would be crafted that enabled community-wide involvement, defined access to cores, and that administered resources and evaluated long-term needs. Initiatives would receive resources to develop and appropriately staff cores. Support for teaching infrastructure and information technology would also be necessary.

Because Harvard Biomedicine Initiatives would not have appointment power, collaboration between the Initiative leadership and the relevant departments is essential. Leaders of Initiatives will provide a planned approach to develop relationships with existing Departments. The advisory group expects that active interactions between Departmental and Initiative leaders would be particularly beneficial for recruiting new faculty. Such collaborations should help to negate the pervasive view of our community as internally competitive and might broaden opportunities for attracting more diverse candidates. While some Departments will have strong representation within a Harvard Biomedicine Initiative, those that do not might invite Initiative faculty to join Departmental search committees when candidates relevant to the Initiative are identified.

Harvard Biomedicine Initiatives will be viewed as jointly "owned" by all of the participating entities. Joint branding of Initiatives would promote shared credit for the successes of these new entities and further community building. Thus, contributions and fund-raising for Initiatives should be shared across institutions. To jump-start the program, however, we suggest that the first and least costly phase of funding (Phase 1,

below) should initially be supported through Central funds, dispensed by a new HMS-based Executive Council (see below). To empower and enable Harvard Biomedicine Initiatives the committee recommended substantial investment to be administered by the Executive Council for 5 years. It is the consensus of the committee that these funds will provide considerable leverage for substantially larger resources.

6. Proposed Mechanism for Challenging the Community to Develop and Expand Harvard Biomedicine Initiatives

Since no single organizational structure is likely to satisfy the needs of all possible communities, the committee proposed mechanism for enabling community building around an Initiative rather than on dictating its form or scope. We envisage several stages at which a community can request funding. These would not necessarily be sequential: in some cases a community's first request for funding might be at the Phase 2 or Phase 3 level.

Phase 1: Convening and defining the community. Grants of up to $250,000 would be available to cross-institutional groups of faculty to bring a community together around a focused Initiative. These funds would be expected to support activities such as a joint seminar program, a retreat, needs assessment (including identifying the need for new faculty and/or enabling technologies), and/or administrative support. Phase 1 Theme grants might have two outcomes: (1) the community decides that the new activities funded by the grant are important, and identifies an alternative source of funding to continue them; or (2) a desire to build a more cohesive community emerges, leading to a detailed proposal for Phase 2 Initiative funding. We imagine that 20 Phase 1 Initiative grants might be awarded in the first 5 years of the program.

Phase 2: Developing a central core. Grants for Phase 2 Initiative projects would likely be in the range of $5-10M, over 2-5 years. These funds would be expected to enable: (1) the creation of new cores by providing matching funding for equipment purchases and by supporting the salary of staff experts; (2) initiation of new high-risk/high-gain collaborative projects that no single lab could attempt; and/or (3) a new educational effort, such as a graduate program or a new undergraduate concentration appropriate for pre-meds. A small number of faculty recruitments might also be made in this Phase, through collaborations with interested Departments. Key to this Phase would be the development of a central governance to support the community, with a defined leadership structure, organizational bylaws, administrative space and support.

Phase 2 Initiative applications would be expected to include consideration of the long-term sustainability of the Initiative: either a plan for attracting outside funds, or defined milestones that would need to be met for funding to continue. We imagine that 5-10 Phase 2 Initiative projects might be funded in the first 5 years of the program.

Phase 3: Faculty expansion. Phase 3 Initiative projects are those in which the scientific and educational opportunities are so significant that the School wishes to create either a

new Department that is inclusive of multiple HMS communities (with appointing powers), or a cross-School Committee. Such projects would require dedicated faculty slots and start-up budgets. They would need to create a sustainable Executive Committee structure with a direct reporting line to the HMS Dean. Phase 3 projects might require a 10-year plan and $50-100M in funding. We imagine that 1-2 such projects might be funded in the first 5 years.

Goals and criteria

The goal of Harvard Biomedicine Initiative seed funding is to create new communities that enable existing investigators to be dramatically more successful. The overall goal is therefore to provide a venue for vibrant new intellectual interactions, mutually supportive mentorship, collaborative fundraising, and the creation of a new cross-institutional identity. Funded programs should meet some or all of the following criteria:

1. Define an integral (not cosmetic) theme for the Initiative that brings disparate parts of the community together, either to achieve a goal that one institution cannot address alone, or to create interdisciplinary interactions that are not possible without a cross-cutting structure.

2. Focus on a major scientific, educational or translational area

3. Develop a community with a sense of inclusiveness and a transparent understanding of criteria for membership.

4. Enable grass-roots participation with reasonable consensus on goals and leadership.

Community structures such as the ones discussed in Section 3 would meet the above criteria, but other structures may be possible.

Funding:

For the success of Harvard Biomedicine Initiatives, considerable investment will be required – expenses that must be shared by the collaborating institutions. While the subcommittee encouraged leadership by HMS particularly for initial Phase I funding and project management (approximately $5 million), we strongly endorsed participatory fiscal management for the duration of these Initiatives. Projected budgets for the Phase II efforts approach $25-50 million yearly over 5 years and for Phase III effort (2-3 projects), approximately $50-100 million dollars yearly over 5 years. These costs are expected to be partitioned among the participating HMS biomedical institutions, paralleling the size and role of each in the initiative. While establishing fiduciary models was beyond the purview of the subcommittee, we envisioned mechanisms similar to those employed in the recently successful CTSA grant, as a cost-sharing strategy that benefited all.

Recognizing that today the Harvard biomedical community receives ~1 billion dollars/year in indirect costs from federal and other granting sources, the projected investment in these endeavors represents a small fraction (2-5%) of the indirect costs

received by each of the Harvard institutions. Moreover, the subcommittee expected that the new research missions enabled by these Initiatives will attract significant financial support from philanthropy, funding agencies (NIH) and industry partners, as has clearly occurred at the Broad Institute, which began with a comparable level of investment. Beyond tangible returns, these investments have enormous to create a new culture for the Harvard biomedical community, one based on cross-institutional collaborative research that engages a wide community of the brightest students and accomplished faculty.

7. GOVERNANCE OF HARVARD BIOMEDICINE INITIATIVES

The committee proposes creation of a Harvard Biomedicine Executive Council for the governance of Initiatives. While based at HMS, the Executive Council should be constituted from senior leadership with diverse expertise from within the broad Harvard biomedical community. We identified both philosophical and pragmatic functions for the Executive Council that would benefit Initiatives and at large biomedical community as HMS and Harvard hospitals. These include:

1. Set challenges for HMS community;
2. Align Initiatives with changing funding opportunities at NIH (or not, depending on the importance and novelty of the goal);
3. Help to link Initiatives with HMS and Harvard Hospital goals;
4. Define mechanisms to promote flexible and timely Initiatives;
5. Establish transparent mechanism for funding new Initiatives;
6. Establish review processes for proposed and existing Initiatives;
7. Define mechanism to terminate or transition Initiatives;
8. Set criteria for resource allocation for Initiatives.

The committee recognized and endorsed the concept that the Harvard Biomedicine Initiatives Executive Council would have functions that parallel those of HUSEC, albeit with an HMS focus. We also recognized that strong inter-institutional leadership on the Council would facilitate collaborative fund-raising efforts envisioned for long-term support of Initiatives and would promote an interactive community at the highest levels of HMS.

Expanding Organizational Structures to Promote Harvard-wide Collaboration
The committee identified multiple specific obstacles that hinder collaborations even between faculty from two institutions within our community. These barriers will be even greater for multi-institutional faculty who develop Harvard Biomedicine Initiatives. Challenges to collaboration include each institution's independent regulatory boards that oversee the participation of human subjects in research or animal care and use committees, corporate sponsored research and licensing offices, and dissociated grants management systems. Further discussion of administrative barriers that impeded collaboration across HMS and Harvard hospitals are detailed in accompanying Appendix 1, and in the report from the Tools and Technologies advisory group.

While the subcommittee appreciated that many historical, medico-legal, and financial reasons account for the multiplicity of administrative structures, we uniformly agreed that these constitute real factors that inhibit collaborative research and teaching among faculty. In addition to increasing the administrative burden of research, the multiplicity of required procedural rules and regulations and associated oversight committees increases costs for all institutions. These barriers reinforce the perception that collaboration at Harvard is arduous, which propels students and faculties toward other institutions.

Harvard has witnessed a successful joint venture with the development of Partners Healthcare from two fervent clinical competitors, the Brigham & Women's Hospital and Massachusetts General Hospital. Harvard has also realized impressive research and teaching opportunities from the creation of the Dana-Farber/Harvard Cancer Center and the Broad Institute, the subcommittee concluded that viable partnerships among all of the entities that comprise HMS are entirely feasible. While we see important reasons to preserve intrinsic identities of each hospital and the medical school, the committee is certain that stronger institutional partnerships, both between HMS and Harvard hospitals and among Harvard hospitals would greatly benefit our shared missions of research and teaching.

The Organizational Structures subcommittee challenges the leadership of HMS and all Harvard hospitals to break down the barriers between institutions that impede collaborations. Whether this requires a re-evaluation and/or restructuring of charters, agreements or legal documents, the committee is certain that strategies can be found to seamlessly enable inter-disciplinary, inter-institutional science and education.

While the committee envisioned great opportunities that would ensue from the creation of a single united biomedical entity that encompassed the entire HMS community, we also recognize that restructuring corporate relationships between all HMS institutions was not our charge. However, we found that many barriers inhibiting strong and vigorous collaborations in research and education are the byproduct of these complex relationships. We urge considerably more thought and examination of new strategies to unite our community. As a minimum, we ask that HMS and Harvard hospitals address in a timely fashion to eliminate regulatory and administrative burdens between our collective institutions. If HMS and Harvard hospitals are to have continued success in biomedical research and education, we must be able to work together.

APPENDIX 1. STRUCTURAL AND CULTURAL ISSUES THAT INHIBIT COLLABORATION.

One major impediment to collaboration across institutions is the need for multiple, distinct regulatory reviews. Obviously there will continue to be IRBs and IACUCs that are specific for each institution (in fact this is mandated). Nonetheless, there are several changes in the current structures that would facilitate collaborative studies across institutions. This would also improve the scientific studies for many individuals.

1. **IRBs.** The forms to be filled out should be the same across institutions; this would clearly decrease the burden on investigators who wish to carry out collaborative work. Approval by the institutional IRB of one of the HMS constituents might, at least under certain circumstances, allow expedited review by other HMS institutional boards. This might also resolve issues of prioritization of studies. If there are multiple open studies within one institution there are currently mechanisms in place for prioritization among the studies. However in some instances there are multiple studies across institutions that might be equally appropriate (i.e for tissue use). At present there is no venue for reconciliation among the distinct studies in different institutions. This change in structure would be of benefit to all faculty members, and to the scientific endeavors of these institutions.

To achieve this, there would need to be financial support for the initial task of reconciling the IRB forms. In addition, there would need to be an ongoing mechanism of discussion across the different IRB committees.

2. **IACUC.** The forms for the distinct IACUCs should also be the same across institutions. Again this might enable facilitated or rapid review of a protocol previously approved by a neighboring institution. A further impediment to collaborative research with animals is the lack of animal facilities and animal testing systems accessible to investigators from multiple institutions. The recent construction of several buildings that include laboratories from several institutions (i.e the Lyme building –new name) might provide a place for housing animals to be used by multiple investigators, and/or ones that will undergo batteries of specialized tests that are found only in certain sites, whether specialized imaging or specialized behavioral testing.

3. Grants Management: Grants submitted by investigators are submitted through home institutions, thus significantly hampering inter-hospital collaborations due to the burden of generating sub-contracts with other Harvard institutions. To address this problem, we propose a Harvard-wide Center for Grants management that would work with the various host institutions and provide support to teams of investigators that wish to collaborate. This central office can then dispense funds (both direct and indirect costs) to the various investigators and institutions depending on their individual contributions. In the era of paper-less grants submission, in theory this could even be done in virtual space or out-sourced (although with confidential scientific data). HMS allows centralized grants submission for certain foundation grants (such as Pew or Burroughs Wellcome) already, hence the template for such an effort already exists.

4. Tech Transfer: The goals are to maximize the intellectual property position of the university's innovation and providing easier access for innovations arising from Harvard to be presented to the industry and venture capital community. Currently, the tech transfer offices across the various institutions do not talk openly with each other, and more often compete with each other, which often hinders progress in getting innovation to patients. Moreover, the rules and regulations for distributions of royalties are quite different across the various Harvard institutions. HMS should lead the way and propose over-arching guidelines. Likewise, there should be a single conflict-of-interest policy that should be proposed by HMS and be enforced at the various institutions. The idea that institutions have their own, on top of what HMS requires, is cumbersome, confusing, and unnecessary. The preposterous idea of exchanging MTAs between different Harvard institutions when reagents are shared should be abolished. There should be free exchange of reagents and materials across all Harvard institutions for research purposes. Other institutions such as the University of California hospitals (may be even larger than the Harvard institutions) have a central office of technology transfer and campus specific tech transfer offices.

APPENDIX 2: MEMBERS OF THE ORGANIZATIONAL STRUCTURES SUBCOMMITTEE

Committee Leaders

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