# SURVEYING THE NEED FOR ''TECHNOLOGY MANAGEMENT FOR GLOBAL HEALTH'' TRAINING PROGRAMS

Usha R. Balakrishnan,<sup>1</sup> Lisa Troyer,<sup>\*2</sup> Edwin P. Brands<sup>3</sup>

<sup>1</sup>Centre for the Management of Intellectual Property in Health Research and Development - USA (MIHR-USA), 33 Buchanan Court, Iowa City, IA 52246; usha@mihr.org
 <sup>2</sup>Department of Sociology, University of Iowa, Iowa City, IA 52242; lisa-troyer@uiowa.edu
 <sup>3</sup>Department of Geography, University of Iowa, Iowa City, IA 52242; edwin-brands@uiowa.edu

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#### **EXECUTIVE SUMMARY**

Technology licensing office (TLO) managers in universities have begun to address the issue of applying intellectual property (IP) management tools in the context of global health. TLO managers typically perform a multitude of tasks, from evaluating inventions for patentability and marketability, to educating researchers on key IP issues, to crafting licenses that are mutually beneficial to researchers, the university, and private industry. With the purpose of enhancing public benefit through technology transfer, TLOs often need to -- as could be expected due to the high cost of patent prosecution -- evaluate profitability and commercial potential in their decision-making. Increased TLO manager consideration of the potential contributions of new health R&D and product innovations to address important global public health goals (i.e., reduction of disease burdens among millions of affected poorer populations in developing countries) will require forging new collaborative relationships, incorporating creative licensing practices, and embracing "global public good" within academic and research communities. In this paper, we report on the results of a survey designed to identify and document opportunities and barriers to the management of discoveries and inventions arising from global health (GH) research outcomes at a number of academic and research institutions in the US and Canada.

Our two-part survey was anonymously administered to a sample of U.S. and Canadian institutional affiliates of AUTM members. Part I of the survey was aimed at gathering descriptive information about the TLOs; whereas Part II was aimed at decision making processes and and barriers to, experience with, and interest in promotion of global health-relevant discoveries. An overall response rate of approximately 56% was achieved. Eighty percent of responding TLOs had less than \$4 million in annual licensing income. The median TLO is relatively small with two professionals and one support staff, processing 34 disclosures and executing six patent licenses/options, with a licensing income of \$700,000 and external research dollars between \$20 and \$90 million, annually

Patentability and long-term commercialization were rated highest in terms of importance of criteria in general evaluation of patents and disclosures. However, a lack of income generation potential was not viewed as a major barrier to promoting global health related inventions. The lack of global health related invention disclosures, followed by a lack of external funding for global health related research, were viewed as the greatest obstacles. We

suspect that these two factors are interrelated: The lack of funding is likely to affect research, which drives inventions (and subsequently disclosures for evaluation by TLOs).

Public-private product development partnerships have recently emerged as one of the key elements in developing global health technologies. Our survey results suggest that currently, there is a lack of experience among TLO managers with such partnerships: less than one tenth of the survey respondents reported any activity in this area. Our survey also probed TLO directors regarding training and education activities, in general as well as specifically in the area of global public health technology transfer. The vast majority of respondents (>88%) conduct educational seminars; yet, of these respondents less than 5% incorporated a global health component into their seminars.

The final component of our survey gauged the usefulness of potential elements of educational curricula involving global health technology management activities. Respondents rated highly all of the six elements we identified in the survey: including (in order of their ranking) a list of funding opportunities, a list of potential global health partners, sample licensing language, standard humanitarian purpose licensing provisions, case studies, and a directory of experts/technology managers experienced in global health technology management.

The results of our survey indicate that the majority of TLOs are relatively small, and suggest that there is currently a lack of global health management experience among the sample of U.S. and Canadian TLOs that responded to the survey, and that systemic barriers (lack of research funding and lack of inventions) are major obstacles to promoting global health inventions. The lack of experience, partnerships, and seminars/training should be viewed as an opportunity for technology managers to take the lead in raising their own awareness and that of researchers as well as potential public and private donors and product developers in order to enhance our collective ability to address significant and pressing global health challenges.

### **1.0. INTRODUCTION AND BACKGOUND**

Technology licensing office (TLO) managers in universities have begun to address the issue of applying intellectual property (IP) management tools in the context of global health. TLO managers typically perform a multitude of tasks, from evaluating inventions for marketability, to educating researchers on key IP issues, to crafting licenses that are mutually beneficial to researchers, the university, and private industry. With the purpose of enhancing public benefit through technology transfer, TLOs often need to -- as could be expected due to the high cost of patent prosecution -- evaluate profitability and commercial potential in their decision-making. Increased TLO manager consideration of the potential contributions of new health R&D and product innovations to address important global public health goals (i.e., reduction of disease burdens among millions of affected poorer populations in developing countries) will require forging new collaborative relationships, incorporating creative licensing practices, and embracing "global public good" within academic and research communities. In this paper, we report on the results of a survey designed to identify and document opportunities and barriers to the management of discoveries and inventions arising from global health (GH) research outcomes at a number of academic and research institutions in the US and Canada.

### 1.1. The Bayh-Doyle Act of 1980

The passage of the Bayh-Dole Act of 1980 transformed university-based patenting functions and academic-industry liaison mechanisms in the United States. By enabling universities to legally retain title to and license inventions and discoveries resulting from federal sponsorship of research, the Bayh-Dole Act triggered (a) the formation of numerous formal technology licensing offices (TLOs) on US university campuses, and (b) the development of a cadre of "technology transfer" professionals, most whom now belong to the professional society, the Association of University Technology Managers (AUTM). AUTM was launched in 1974 as the Society of University Patent Administrators with 50 members. Its total membership (US and international) now exceeds 3,000<sup>1</sup>.

### 1.2. The Work and Impact of TLO managers

TLO managers typically are faced with significant learning curves in not only sciences, but also in law and business practices. TLO managers routinely interact with researchers from a variety of scientific disciplines as well as executives from diverse industrial sectors. In this sense, TLO managers serve as "cultural translators," or bridges between several professions, academic disciplines, industry, and technology sectors. Such complex and intense experiences over a period of time enable TLO managers to appreciate and balance their roles and various expectations within the technology transfer system. TLO managers can be likened to artisans in that they develop specialized and customized approaches in real-time to managing inventions, inventors, licensees and the entire negotiation process involved in complex deal-making.

Because of the significant expenses involved in filing patent applications and protecting intellectual property rights, TLO managers make their decisions on whether or not to proceed with patent filings primarily on the basis of two criteria: patentability and commercial potential, including an assessment of whether a third party sponsor or licensee is willing to reimburse the TLO for patent prosecution expenses.

TLO managers' typical functions and activities include:

- Receiving invention disclosures from university researchers
- Educating and advising researchers on intellectual property/patent policies and procedures
- Evaluating disclosures for patentability and commercial potential
- Engaging patent lawyers to file, prosecute, maintain and enforce intellectual property based on invention disclosures
- Commercializing inventions through 1) marketing and 2) negotiating license or other contractual agreements to formalize collaborations with industry partners
- Monitoring licensees for compliance with contractual terms
- Disbursement of royalty proceeds to various stakeholders
- Reporting periodically to research sponsors under various federal funding and other regulations, policies and guidelines

<sup>&</sup>lt;sup>1</sup> AUTM: 30 years of innovation, booklet distributed at the AUTM 2004 conference.

Patent filing decisions and subsequent licensing tactics and negotiation strategies employed by a TLO manager significantly impact sequential trajectories and development pathways involved in translating nascent university-based discoveries into products that benefit society. TLO managers thus are key "gatekeepers," and their managerial role in facilitating timely interactions within the continuum of scientific R&D, discovery and product development is critical.

## **1.3.** Managerial Challenges: Balancing TLO Mission, Operational Strategy, Current Pressures

The TLO's primary mission is to ensure that the fruits of publicly-funded research are translated into products for the benefit of the public. From the managerial viewpoint, this primary mission then guides the development of operational strategies. However, this is a difficult balancing act given the nature of the academic patent licensing environment, where commitments of \$15,000 (or more in the case of complex biotech patent prosecution) are made per patent filing. Financial commitments of this nature create pressure both within TLO operations and from university administration for TLOs to generate substantial funds for the institution to (a) justify sustained investments in TLO staffing and operational budgets, and (b) enhance prospects for additional revenue-producing patent portfolios under TLO management over the short and long term.

Due to recent budgetary shortfalls in many US states, there is increased pressure for TLOs at public universities to render more local and regional economic development benefit through technology transfer in terms of increased start-up businesses (e.g. entrepreneurial activities, incubator centers) and TLO participation in business recruitment activities (university research parks as ideal site locations for high tech companies).

Despite facing pressures from multiple constituencies, and working through daunting project caseloads, some TLO managers have recently begun to discuss IP management challenges in the context of global health. Such discussions have gained momentum within AUTM and led to the recent organization of the special interest group, Technology Managers for Global Health (TMGH) in partnership with Oxford, UK-based MIHR (Centre for the Management of Intellectual Property in Health R&D). Based on discussions held within TMGH, we have found enormous enthusiasm to belong to an informal resource network to (i) address IP and global health concerns on an ongoing basis, and thereby, raise the general level of awareness and sensitivity among AUTM colleagues, and (ii) gather and generously share a growing collection of relevant experiences through informal and/or formal mechanisms to a large number of AUTM as well as non-AUTM professionals.

Facilitating the training of TLO managers who want to actively consider the global health implications of their work is an essential step in enabling individuals and institutions to launch their own forays in this area. This type of training may lead to uniquely refined roles for TLO managers and their institutions in promoting global health partnerships. Much as technology transfer activity has evolved over the last three decades, such new training and ensuing dialogs may help formulate new approaches and models that universities may utilize to catalyze partnerships in the global health arena. Enabling a more effective pursuit of TLO's "public benefit" mission in this way has the potential to extend the impact of TLO managers' (and their institutions') work into much broader global contexts.

### 2.0. SURVEY OF US TLO MANAGERS<sup>2</sup>

The purpose of our survey is to systematically identify and document barriers to the management of discoveries and inventions arising from global health (GH) research outcomes confronted by TLO managers. Discoveries and inventions arising from GH research may not fit the profile of "conventional" types of innovations with which TLO managers are familiar. Our survey systematically assesses this concern to gain a more complete understanding of how the unique profile of innovations from GH research fits (or does not fit) within the structure of existing technology licensing decision-making and procedures. This understanding, in turn, could inform the development of curriculum for training TLO managers in GH.

The two-part questionnaire (see Appendix A) contained 13 questions: Part I requested descriptive information (e.g. external research dollars, age of TLO office, number of invention disclosures) regarding TLOs and institutions. Part II was aimed at specific activities pertaining to decision-making, and barriers to, experience with, and interest in promotion of GH discoveries in TLO offices. To avoid conflict of interest for the first author (Balakrishnan), only the second author (Troyer) was involved in the data collection and analysis and only she has access to the data.

### 2.1. Sampling & Response Rate

The AUTM membership's institutional affiliations comprised our sampling frame. One questionnaire was sent via postal mail to the director of each technology licensing office represented by the membership in the United States and Canada. Mailing labels were purchased from AUTM for this purpose and a pre-addressed stamped return envelope was included in the mailing. The instructions indicated that respondents should reply anonymously, without indicating their identity on the questionnaire. We mailed 385 questionnaires; 240 were returned for an initial response rate of 62.34%. Of these, 24 did not answer any of the survey questions, leaving an analyzable response rate of 56.10% (n=216). Among these analyzable cases, some respondents did not answer all of the questions. (The number of valid cases for each question is given in the tables.)

### 2.2. Descriptive Profile of Technology Licensing Offices

Table 1 reports the characteristics of the TLOs in our sample. A comparison of the mean and standard deviation with the median in Table 1 reveals that the sample is somewhat skewed, with a few very large offices driving up mean values. For example, only 40 respondents out of 198 (20.2%) reported licensing income above four million dollars. This suggests that the median may provide a more accurate measure of central tendency for this sample. More importantly, it suggests that respondents to our survey primarily represented relatively small offices. As this table indicates, about half of the offices in our sample have been in existence for 11 or fewer years. The median office is relatively small with two professional and one support staff, processing 34 disclosures and executing six patent licenses/options, with a licensing income of \$700,000 and external research dollars between \$20 and \$90 million, annually.

<sup>&</sup>lt;sup>2</sup> The protocol and instrument for our survey was approved by the University of Iowa's Institutional Review Board (IRB #200503752).

		MEDIAN
CHARACIERISIIC	MEAN (SD)	MEDIAN
Age of Technology Licensing Office (in years) $(n = 210)$	14.68 (11.79)	11
Number of Professional Staff ( $n = 213$ )	3.46 (5.49)	2.0
Number of Support Staff ( $n = 213$ )	2.54 (4.17)	1.0
Number of Invention Disclosures in 2004 ( $n = 207$ )	79.82 (120.89)	34
Number of Patent Licenses/Options Executed in 2004 (n = 204)	20.33 (35.73)	6
2004 Licensing Income (in millions) ( $n = 198$ )	4.38 (1.15)	0.70
External Research Dollars Received (in millions) (n=213)	N/A	\$20 - \$99

## Table 1. Mean, Standard Deviation, and Median for Characteristics of Technology Licensing Offices in the Sample

We also found that the majority of respondents indicated reporting to a Research Office (62.5%). The second-most common reporting line was to either an Academic Affairs Office (including Provost) or President (12.5% each). The next most common reporting line was to a Foundation Office (9.2%). Reporting lines to Corporate Affairs, Public Affairs, or other offices were less common, with just 4.6% indicating reporting to one of these institutional entities.<sup>3</sup>

## **2.3.** Factors Affecting Evaluation of Patents/Disclosures and Attention to Global Public Health Technologies

Our interest is in identifying opportunities for advancing technologies related to global public health. Consequently, a necessary first-step is to understand the decision-making process around technology in general. We asked respondents to report on the relative importance of eight criteria that might affect evaluations of technology. Respondents indicated on a scale from one (Not at All Important) to seven (Extremely Important), with the scale mid-point of four (Somewhat Important) the importance of the criteria in Table 2.

Table 2.	. Means and Standard Deviations for Importance	e of Criteria in	<b>Evaluation of</b>
Patents/I	/Disclosures		

CRITERION	MEAN (SD)
Patentability $(n = 216)$	5.94 (0.97)
Availability of Budgetary Resources for Patenting $(n = 216)$	4.48 (1.80)
Anticipated Availability of $3^{rd}$ -Party Reimburser for Patent Costs (n = 216)	4.63 (1.72)
Immediate Commercialization Prospects	4.75 (1.41)
Long-Term Commercialization Prospects $(n = 216)$	5.86 (1.20)
Research Funding Prospects ( $n = 216$ )	4.06 (1.65)
Potential for Forming Start-Ups to Aid Local Economic Development ( $n = 216$ )	4.12 (1.61)
Ability to Promote Development of Inventions & Technologies that Address	3.46 (1.80)
Treatments for "Diseases of Poverty" $(n = 189)$	
Other $(n=27)^*$	5.44 (1.87)

<sup>&</sup>lt;sup>3</sup> Total sums to more than 100% because some respondents indicated multiple reporting lines.

\*Respondents were permitted to suggest criteria other than the eight that we listed and to provide a rating of the importance of each criterion that they suggested. Other criteria mentioned included interest of researchers, interest of administrators, institutional strategic initiatives.

As these results indicate, patentability (mean = 5.94) and long-term commercialization (mean = 5.86) were rated highest in terms of importance, with "other" criteria (mean = 5.44) related to interests of administrators and researchers, as well as the strategic initiatives of the institution. Technology related to treatments for "diseases of poverty was rated least important; yet, came in around the scale mid-point (i.e., "somewhat important"). Indeed, as Table 2 shows, on average, all of the criteria except technologies related to treatments for diseases of poverty" were more than "somewhat important." The results are suggestive of the importance of financial drivers and direct economic implications in evaluations related to patents/disclosures.

From a programmatic standpoint, these results may indicate the importance of making the economic implications of attention to technology related to treatments for neglected diseases salient. That is, to facilitate the embrace of the "global public good" on the part of academic and research communities, there must be a broader understanding of and appreciation for the economic impact that attention to neglected diseases has the potential to impart.

To drill down further into the decision-making processes within TLOs related to global public health, we asked respondents to rate the extent to which different factors obstructed the pursuit of technology transfer related to global public health within their offices. The response scale for these factors ranged from one (Not at All an Obstacle) to seven (Substantial Obstacle), with a scale mid-point of four (Somewhat of an Obstacle). Table 3 provides the means and standard deviations for these factors.

Table 3.	Means and Standard Deviations for Extent to which Factors are an Obstacl	le in
the Purs	uit of Technology Transfer Related to Global Public Health	

FACTOR	MEAN (SD)
Lack of Faculty Research/Interest (n = 189)	4.08 (2.06)
Lack of Reasonable Flow of Global Health-Related Invention Disclosures (n =	5.49 (1.39)
189)	
Lack of Expertise Within Office in Area of Global Public Health Inventions (n =	3.24 (1.79)
189)	
Lack of Revenue-Generating Potential from Global Public Health Inventions (n=	3.64 (2.08)
183)	
Lack of External Funding Available for Global Public Health Research (n = 168)	4.38 (2.06)
Lack of Relationships with Professional Organizations or Networks with Goals	4.15 (1.78)
of Advancing Global Public Health Partnerships $(n = 177)$	
Lack of Support from Senior Administration $(n = 180)$	2.68 (1.93)
Lack of Time to Allocate to Projects with Less Income-Generating Potential (n =	3.92 (1.96)
183)	
Other $(n = 6)^*$	6.00 (1.10)

\* Respondents were permitted to suggest criteria other than the eight that we listed and to provide a rating of the extent to each criterion that they suggested was an obstacle. Other factors

included "Not a strategic priority"; "Not enough personnel"; "Lack of Awareness of What Inventions Are Related to Global Public Health"

Recall our earlier findings reported in Table 2 regarding the role of financial and economic criteria in the evaluation of patents/disclosures. It may seem paradoxical at first that "Lack of Time to Allocate to Projects with Less Income-Generating Potential" and "Lack of Revenue-Generating Potential from Global Public Health Inventions" are viewed as less than "Somewhat of an Obstacle," on average, in the pursuit of global public health technologies. (respectively, mean = 3.92 and mean = 3.64). Yet, these survey items reflect a fine distinction from those in Table 2. The items in Table 2 reflect factors that generally weigh-in on evaluations of patents/disclosures, whereas the items in Table 3 reflect barriers to global public health technology transfer, in particular. In other words, it may be that while positive financial and economic effects are important in the general evaluation of patents, TLO directors recognize that other factors may legitimately govern inventions and discoveries related to technology transfer within the global public health (and perhaps other) domains. On a related point, note that "Lack of Support from Senior Administration" is, on average, viewed as less than "Somewhat of an Obstacle" (mean = 2.68). This further supports the notion that institutions may not be entirely driven by financial and economic concerns in the arena of technology licensing activities. Moreover, it again suggests that education may be a key and very effective strategy for enhancing technology transfer as it relates to global public health. Later, in section D, we will further examine such educational strategies.

As Table 3 indicates, the greatest obstacles were those respondents suggested under "Other." These results, however, must be interpreted cautiously, since only six respondents suggested additional factors. Aside from the "Other" factors, the factor viewed, on average, as the greatest obstacle was "Lack of Global Health-Related Invention Disclosures" (mean = 5.49), followed by "Lack of External Funding for Global Health-Related Research" (mean = 4.38). We suspect that these two factors are interrelated: The lack of funding is likely to affect research, which drives inventions (and subsequently disclosures). This suggests two programmatic directions. First, institutions seeking to increase technology transfer related to global public health must help researchers identify external funding. Second, they must develop strategies to advocate for attention to global health on the part of external funding agencies and foundations. This latter direction reiterates a common theme in our research: The need to educate researchers, funding agents, and the public regarding the potential positive economic and social impacts of attention to global public health. The former direction (i.e., identify funding opportunities) might also address other factors that are greater obstacles, such as faculty interest. The identification of funding opportunities may pique faculty interest in pursuing research that leads to technologies and inventions that address global public health issues, although note that lack of interest is just barely above the scale midpoint, corresponding to "Somewhat of an Obstacle."

Table 3 also foreshadows a potentially important strategy for moving in these directions. Note that "Lack of Relationships with Professional Organizations or Networks with Goals of Advancing Global Public Health Partnerships" is, on average, slightly more than "Somewhat of an Obstacle" (mean = 4.15). We are able to further explore this finding through the results presented in Table 4. This table reports number of respondents reporting that their TLO was engaged in specified partnerships within the last year.

PARTNERSHIP	FREQUENCY
International AIDS Vaccine Initiative $(n = 213)$	15
Medicines for Malaria Venture $(n = 210)$	12
Malaria Vaccine Initiative/PATH ( $n = 213$ )	15
Global Alliance for Tuberculosis Drug Development (n=213)	21
Aeras Global Tuberculosis Vaccine Foundation ( $n = 210$ )	0
International Partnership for Microbicides $(n = 213)$	n < 5
Pediatric Dengue Vaccine Initiative $(n = 213)$	n < 5
Foundations for Innovative New Diagnostics $(n = 213)$	6
Institute for OneWorld Health ( $n = 216$ )	15
Drugs for Neglected Diseases Initiative $(n = 213)$	0
Other $(n = 16)^*$	18

#### Table 4. Frequency of TLO Partnerships Related to Global Public Health

\*Other partnerships mentioned were MEND, GTI, PIPRA, FIND, Grand Challenges in Global Health, Global AIDS Vaccine Initiative, Doctors Without Borders, Rotary International, Private Corp. for HIV Vaccine.

Perhaps the most compelling result suggested by Table 4 is the dearth of partnerships. This may signal that there is a lack of experience with respect to such partnerships among TLO managers. Overall, there was very little reported activity involving these global health-related public-private partnerships. The Global Alliance for Tuberculosis Drug Development showed the most activity (respondents from 21 offices). Yet, this still represents less than 10% of the sample. Thus, programmatic attention might be given to facilitating ties between TLO managers and staff with such partners and networks. For instance, proactive site visits to institutions, joint conferences, and the development and dissemination of curricular training materials that include lists of such organizations may catalyze more research in this arena. This represents one educational opportunity. We turn now to a systematic investigation of other opportunities.

#### 2.4. Education & Training Related to Global Public Health Technology Transfer

The above analyses provide a strong indication of the potential for making an impact on the level of activity related to global public health technology transfer through training and education channels. Our survey also probed TLO directors regarding training and education activities, in general and related specifically to global public health technology transfer. We found that 192 of 216 respondents to this question (88.9%) reported conducting educational seminars. This is encouraging insofar as it suggests the recognition that ongoing training is critical to the rapidly evolving field of technology transfer. Yet, of these 192 respondents reporting the presence of educational seminars at their institutions, only nine (4.7%) indicated that they incorporated a global health component in their seminars. While on the face, this may seem discouraging, we view it as an important opportunity. To further exploit the emergence of this opportunity, we asked respondents to report on the value of different elements that might comprise training and educational seminars related to global public health. Respondents were asked to rate the usefulness of elements of curricula to enhance global public health management activities.

Responses were made on a scale from one (Not at All Useful) to seven (Extremely Useful), with a scale mid-point of four (Somewhat Useful). Table 5 summarizes these results.

## Table 5. Means and Standard Deviations for Usefulness of Potential Elements of Educational Curricula Involving Global Public Health Management Activities

CURRICULUM ELEMENT	MEAN (SD)
Case Studies $(n = 180)$	4.78 (1.56)
Sample Licensing Language (n = 192)	5.05 (1.79)
Standard Humanitarian Purpose Licensing Provisions (n = 186)	5.03 (1.72)
List of Potential Global Health Partners $(n = 183)$	5.52 (1.50)
List of Funding Opportunities $(n = 189)$	5.75 (1.69)
Directory of Experts/Technology Managers Experienced in Global Health	4.71 (1.59)
Technology Management ( $n = 189$ )	
Other $(n = 15)^*$	5.80 (2.48)

\* Respondents were permitted to suggest elements other than the six that we listed and to provide a rating of the extent to which the elements that they suggested would be useful. In nearly every case in which a designation was made under "Other," however, the elements listed were not given or were redundant with the categories above. Consequently, this result is not interpretable.

Perhaps the most striking feature of Table 5 is that all of the six elements were rated as more than "Somewhat Useful." Aside from the "Other" category (which, as indicated by the table note, is not interpretable), the most useful criteria, on average, appear to be "List of Funding Opportunities" and "List of Potential Global Health Partners" (respectively, mean = 5.75 and mean = 5.52). This highlights the importance of knowing "who" and "where," when it comes to supporting technology licensing activities. To the extent that global public health technology transfer activities may be emergent among the academic and research institutes we surveyed, the need for this information may be particularly keen.

The results in Table 5 also suggest the importance of providing template processes, language, and provisions related to licensing global public health technologies. Respondents indicated that sample licensing language, standard humanitarian purpose licensing provisions, and case studies would all be more than "Somewhat Useful" in the development of education and training seminars related to global public health management activities (respectively, mean = 5.05, mean = 5.03, mean = 4.78).

Finally, the importance of human resources is indicated in Table 5. Respondents indicated that a Directory of Experts/Technology Managers Experienced in Global Health Technology Management would be useful in developing curricula (mean = 4.71). Until activities surrounding global public health technology management become more common, experts may not be highly visible. Consequently targeted efforts to identify them and encourage others to seek their expertise may facilitate advances in global public health technology management.

### 2.5. Study Limitations

We would be remiss not to remark on the limitations of our research. First, although the response rate (56.10%) falls within the rule of thumb for "adequate" with respect to surveys of this nature (i.e., anonymous, sent via postal mail, see for example, Puck (2003)), it is always reasonable to consider the biases that may be reflected in a less-than-100% response rate. In this case, it was clear from our cover materials and the questionnaire itself that our interest was in examining technology transfer as it relates to global public health. Non-respondents may be those less interested in this area or those who face formidable barriers to such pursuits (such as institutional lack of support). Consequently, a conservative interpretation of these results would be to limit any generalizations to groups with at least a minimal interest in and institutional support for the pursuit of global public health technology transfer. Nonetheless, this represents a substantial number of institutions and individuals.

Second, it is important to recognize the profile of the institutions whose representatives participated in our study. As reported in section A, most of them are relatively small institutions in terms of both staff size and level of activity. Yet, these may be precisely the kinds of institutions at which resources (especially information and human resources) are particularly scarce, making advances in an emergent area, such as global public health technology management very challenging.

Third, on a related point, our survey represents a "snapshot" in time regarding a limited set of factors affecting global public health technology management activities. It is unclear what the longitudinal trends are with respect to our findings. Moreover, there may be other variables, which we did not systematically explore, that affect these activities (e.g., local, regional, and global economic conditions; advances in complementary technologies; local, regional, and global events).

### 3.0. DISCUSSION AND CONCLUSION

Despite the limitations that we have inventoried, we believe that the results of our research do shed new understanding on the processes surrounding global public health technology management activities. First, although financial and economic considerations generally drive technology management activities and may have the potential to stymie activities that are less likely to generate revenues or directly affect local economic development, this does not close the door to the pursuit of global public health technology transfer. Rather, it suggests the importance of educating technology licensing professionals, researchers, and institutions regarding the economic impact of global public health technologies. An important element of such education is likely to be the broader (both geographically and temporally) view that is needed to recognize the importance of embracing "global public good" from social, economic, and humanitarian standpoints. The field for such education may be particularly fertile, insofar as our survey results suggested that TLOs do not (on average) experience resistance from senior administrators when it comes to global public health technology management activities. Thus, once "planted," the seeds of education may lead to a bountiful blossoming of new efforts and successes in global health technology management.

Second, our research suggests specific avenues that may be taken to enhance global public health TLO activities. Aside from general education regarding the positive social,

economic, and humanitarian effects of promoting global public technology transfer, our investigation suggested that there may be a promising opportunity to educate TLOs regarding the process through which global health technologies are effectively managed.

Third, and related to the second point, the results of our survey suggest that human resources may be a particularly important resource. More specifically, brokering professional relationships between those with and those without experience in global health technology management activities appears to be vital to enhancing these activities. This may be a particularly "low hanging fruit" that can be rapidly harvested. The recent formation of the AUTM special interest group, "Technology Managers for Global Health" (TMGH), in parternship with the Centre for the Management of IP in Health R&D (MIHR), provides a kind of "human resources warehouse" of interested and experienced professionals. These are the likely candidates to become resources for TLOs with an interest in advancing their global public health technology management activities.

In conclusion, as bridges between professions, academic disciplines, industry, and technology sectors, TLO managers are uniquely positioned to influence technology transfer. Yet, establishing and/or strengthening such bridging roles requires key resources, including access to professional networks, legitimacy within one's own institution, and information and knowledge. These resources are not always easy to secure and are often very difficult to disseminate to others, particularly when they involve an emerging area of activity, such as global public health technology management. It is no secret that ongoing training is of central importance to TLOs (and our research confirms this). Systematically identifying the strategy for training to capitalize on new opportunities, such as those related to global health, however, is not always undertaken. We believe that our work offers an important contribution in this direction.

### 4.0. REFERENCES

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### **APPENDIX A**

### UNIVERSITY OF IOWA SURVEY ON TECHNOLOGY TRANSFER & GLOBAL HEALTH

This survey is being conducted under a collaborative effort, funded by the Rockefeller Foundation (Grant HE039 to Usha Balakrishnan, University of Iowa). Lisa Troyer, Associate Professor of Sociology, University of Iowa, is administering the survey and analyzing the data.

The primary focus of this survey pertains to the work being undertaken by the "Technology Managers for Global Health," a special interest group within the Association of University Technology Managers (AUTM). You are receiving the survey because you are an AUTM member. Participation in the survey is voluntary.

The purpose of the survey is to gather pertinent information that allows for the design and development of targeted training programs for U.S. and Canadian technology managers to foster good practices in the ethical stewardship of intellectual property to promote global health equity.

## Individual responses will be kept confidential. Results of the survey will be reported only in aggregate forms.

The survey is divided into two parts and takes approximately 20 minutes to complete. All answers will remain confidential. Your name or your institution will not be identified with any specific answers you provide. A report of the findings (in summary form) will be made available in the Summer 2005 and will be sent to you, irrespective of whether you complete the survey. The usefulness and quality of the results, however, will depend on the proportion of potential respondents who complete the survey. Consequently, we hope that you will assist us by taking some time to submit your responses to the questions below. If you decide to participate, we would appreciate receiving your completed questionnaire by May 15, 2005.

### PART I

First, we would like to ask you some questions about your institution and technology licensing office.

- 1. Please indicate the total amount of external research dollars received by your university last year by checking the blank beside one of the ranges below.
  - \_\_\_\_\_ a. Less than \$20M
  - b. \$20M \$99M
  - \_\_\_\_\_ c. \$100M \$199M
  - \_\_\_\_\_ d. \$200M \$299M
  - \_\_\_\_\_ e. \$300M \$399M
  - \_\_\_\_\_ f. \$400M \$499M
  - \_\_\_\_\_ g. \$500M or More

2. When was your technology licensing office (TLO) established?

- 3. How many professional staff, in addition to the Director, does the office have?
- 4. How many support staff does the office have?
- 5. How many invention disclosures did your office receive in 2004?
- 6. How many patent licenses/options deals were formally executed by your office in 2004?

7. What was the total licensing income received by your office in 2004?

- 8. Who does your technology licensing office report to in your current organization structure? Please mark all those that apply.
  - \_\_\_\_\_ a. Research Office
  - b. Finance Office
  - \_\_\_\_\_ c. Corporate Affairs Office
  - d. Academic Affairs Office
  - e. Public Affairs Office
  - \_\_\_\_\_ f. President
  - \_\_\_\_\_ g. Other (please specify):

### PART II

Now we would like to ask you some questions about the activities of your office.

9. How **important** are each of the following criteria in the evaluation your office makes of invention disclosures to determine the next step in managing the disclosures or technologies? In the blank beside each criterion, please enter a number from the scale below to indicate how important that criterion is in your evaluation. **Please enter ''8'' if you are unsure about the importance of a criterion.** 

1	2	3	4	5	 7
Not at All		Se	omewhat		Extremely
Important		Ir	mportant		Important

- a. Patentability
- b. Availability of budgetary resources for patenting
- \_\_\_\_\_ c. Anticipated availability of third-party reimburser for patent costs
- d. Immediate commercialization prospects
- e. Long-term commercialization prospects
- f. Research funding prospects
- g. Potential for forming start-ups to aid local economic development
- h. Ability to promote the development of inventions and technologies that address treatments for "diseases of poverty" (e.g., so-called "neglected diseases" such as AIDS, tuberculosis, malaria, chagas, leishmaniasis, African trypanosomiasis, dengue fever).
  - i. Other (please specify):
- 10. Please indicate which of the following Product Development Public-Private Partnerships and entities your technology licensing office has interacted with (including licensing inventions or technology related to "neglected diseases") within the last year. Please check the "YES," "NO," or "UNSURE" column for each partnership/entity.

	YES	NO	UNSURE
International AIDS Vaccine Initiative			
Medicines for Malaria Venture			
Malaria Vaccine Initiative/PATH			
Global Alliance for Tuberculosis Drug Development			
Aeras Global Tuberculosis Vaccine Foundation			
International Partnership for Microbicides			
Pediatric Dengue Vaccine Initiative			
Foundations for Innovative New Diagnostics			
Institute for OneWorld Health			
Drugs for Neglected Diseases Initiative			
Other (Please Specify):			

- 11A. Does your technology licensing office conduct educational seminars for researchers at your institution at least once a year to educate them about patents, intellectual property policies, academic-industry collaborations, and contracting? (Please circle YES, NO, or UNSURE.)
  - YESNOUNSUREIf you circled "NO" for 11A, please skip this question. If you circled "YES," is
  - 11B. If you circled "NO" for 11A, please skip this question. If you circled "YES," is there a "global health" component included in the seminars to provide researchers with information about "neglected health needs" or emerging opportunities to collaborate in global health partnerships? (Please circle YES, NO, or UNSURE.)

### YES NO UNSURE

12. Please indicate the extent to which each of the following factors **obstructs** your office's pursuit of technology transfer activities related to global public health, by entering a number from the scale below in the blank beside each of the items a-i, below. **Please enter ''8'' if you are unsure about whether an item is an obstacle.** 

1	.2	<u> </u>			7
Not at all an Obstacle		Somewhat of an Obstac	ele	Substantia	ıl Obstacle

- a.\_\_\_\_Lack of faculty research/interest in global public health.
- b. Lack of a reasonable flow of global health-related invention disclosures.
- c.\_\_\_\_Lack of expertise within the office in the area of global public health inventions.
- d. \_\_\_\_Lack of revenue-generating potential from global public health inventions.
- e.\_\_\_\_Lack of external funding available for global public health research.
- f.\_\_\_\_Lack of relationships with professional organizations or networks with goals of advancing global public health partnerships.
- g.\_\_\_\_Lack of support from senior administration.
- h.\_\_\_\_Lack of time to allocate to projects with less income-generating potential
- i.\_\_\_\_Other (please elaborate in the space below):
- 13. How useful would each of the following elements of a curriculum be to you to enhance your global health technology management activities? Please enter a number from the scale below in the blank beside each of the items a-g, below. **Please enter ''8'' if you are uncertain about the usefulness of an element.**

1	2		
Not at all Useful	Somev	what Useful	Extremely Useful

- a. <u>Case studies</u>.
- b.\_\_\_\_Sample licensing language.
- c. \_\_\_\_Standard humanitarian purpose licensing provisions.
- d.\_\_\_\_List of potential global health partners.
- e.\_\_\_\_List of funding opportunities.
- f.\_\_\_\_Directory of experts/technology managers experienced in global health technology management.
- g.\_\_\_\_Other (please describe; use back if necessary):

Thank you for taking the time to answer these questions. If you have comments or suggestions that you would like to share with us regarding the management of technology related to global health, please feel free to use the back of this questionnaire. Please put the questionnaire in the pre-addressed, stamped envelope we have provided and drop it in a postal mailbox

### **Attachment: Description of TMGH**

### "Technology Managers for Global Health" (TMGH)

A Special Interest Group within the Association of Univ. Technology Managers TMGH SIG Facilitator: Usha Balakrishnan, University of Iowa (usha-balakrishnan@uiowa.edu) February 2005

### Description

TMGH was established in Summer/Fall 2003 as a Special Interest Group (SIG) within the Association of University Technology Managers (AUTM). An announcement about the formation of TMGH appeared in the November 2003 AUTM newsletter. The inaugural meeting of the TMGH SIG was held at AUTM 2004 in San Antonio. Because of the enthusiastic response from TMGH participants, a very productive second annual meeting of TMGH was held at AUTM 2005 in Phoenix.

If you have case studies or other experiences that to share on these topics, please contact Usha Balakrishnan at <u>usha-balakrishnan@uiowa.edu</u>. We welcome input into these early efforts.

### Purpose

The purpose of TMGH is to serve as a collegial resource and support network for professionals to more effectively:

- (a) manage inventions and technologies that address treatments for "neglected diseases" and other afflictions widely prevalent among the poorer populations in low and middle income countries, and
- (b) compile, discuss and develop standard language in license agreements between universities and companies in higher-income countries which may ensure more widespread development of, or access to, inventions that have both a developing world and "first world" market.

TMGH members will also serve as a resource to other groups and organizations that are engaged in the advancement of global health causes. To this end, several non-AUTM colleagues are now affiliated with, and helping with TMGH activities.

### TMGH collaboration with MIHR: Financial support from Rockefeller Foundation

In September 2004, the Rockefeller Foundation awarded a grant of \$50,000 to the University of Iowa (Usha Balakrishnan is the PI) to formally support collaborative efforts between TMGH and MIHR-Centre for the Management of Intellectual Property in Health R&D (an international nonprofit organization based in Oxford, United Kingdom, see www.mihr.org). The grant supports the design, development and delivery of new training curricula for university managers in the US and Canada to foster best practices in the ethical stewardship of university inventions to promote global health equity.

### Ongoing Activities planned for/by TMGH participants

- Discuss public policy perspectives, IP management challenges and other relevant emerging topics in the context of global public health and equity.
- Propose workshops, seminars, poster sessions, training programs, etc. to (i) effectively heighten awareness, understanding and sensitization to global health issues, (ii) feature ongoing global health efforts and initiatives; (iii) examine new mechanisms for universities to engage in and promote global health partnerships, and (iii) understand potential roles for university professionals in capacity-building in developing countries.
- Build new linkages and actively interact with other organizations to disseminate the work of the TMGH participants at key conferences.
- Gather, compile, develop and disseminate (through a website) a set of "tools" and perhaps an evolving sense of best practices for technology managers to examine and adopt.