

# Must 'MTA' Equate with 'Delay'? Material Transfer Agreements and Institutional Processes in Australian Biomedical Research

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## *Abstract*

*The exchange of tangible materials remains essential to biomedical research, and has become increasingly formalised, including through use of Material Transfer Agreements ('MTAs'). While MTAs provide comfort in clarifying legal relationships, they have not been without problems. Delays in the process of exchanging materials have reportedly epitomised the modern research environment. Most Australian research institutions now have offices dealing in technology transfer and business development ('TTOs'). These offices employ combinations of legal, business and scientific experts. In this article, we explore the impact of TTO practices on the material transfer journey. We present qualitative evidence to demonstrate that resourcing and organisational processes, in addition to levels of experience in MTA processing, affect the pace of material exchange. Our analysis may assist in streamlining transfer processes to a greater extent than standardisation.*

## **1 Introduction**

The modern biological sciences research environment is characterised by legal formalism. Increased focus on commercialisation of publicly funded research is partly responsible because it has fuelled proprietary conceptions of research results and research materials.<sup>1</sup> Research-focused institutions have undergone transformational structural changes focused on capturing industry involvement and commercialisation opportunities. Technology transfer offices ('TTOs') staffed by personnel skilled in law, business or science have become ubiquitous. In Australia, these offices may also be incorporated into business development, industry engagement or commercialisation offices. One outcome of this development is growth in the requirement for written documentation for transfer of tangible materials, in the form of material transfer agreements ('MTAs'). An

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<sup>1</sup> Victor Rodriguez, 'Merton and Ziman's Modes of Science: The Case of Biological and Similar Material Transfer Agreements' (2007) 34(5) *Science and Public Policy* 355.

MTA is a legally enforceable agreement containing terms regulating the exchange of tangible materials and associated data between scientific researchers, and between researchers and commercial suppliers and users.<sup>2</sup>

The devolution of the tasks of negotiation, drafting and execution of MTAs and other contracts to TTO personnel has occurred because researchers engaging in transfers possess neither the skills nor the legal capacity to enter into contracts on their institution's behalf.<sup>3</sup> Even so, the implementation of technology transfer structures within research-focused institutions has been far from uniform.

This paper reports the results of a study focusing on the practices of technology transfer officers relating to material transfers in Australian institutions engaged in biomedical research. It is part of a larger study examining more broadly issues surrounding material transfers within the Australian public research environment.<sup>4</sup> It provides insight into material transfer processes and the effect of institutional structures across various Australian institutions, and speculates on the extent to which they are linked with inefficiencies in the execution of MTAs. It is the first study of its kind to provide specific data on the influence of organisational makeup, processes and levels of experience on the negotiation of MTAs. A glance at universities, and publicly and privately funded research institutes, even within a small jurisdiction such as Australia, reveals different hierarchical structures through which contracts must progress to execution. The parties negotiating, drafting and executing MTAs and other contracts may all have different training and experience, leading to some discord in processes between institutions.

In providing context, Part II overviews previous empirical research investigating the impact of MTAs on the transfer of materials for research purposes. A common theme among these studies is an exploration of whether delays in the transfer of materials slow the pace of biomedical research, and whether these delays may be attributed to the use of MTAs. Part III of this paper delineates our methodology, while Part IV details our results and discussion. It canvasses first, whether delays remain an inherent part of MTA negotiations involving Australian institutions. It then explores grounds for delays encountered during the negotiation process. Part V presents our conclusions. A primary conclusion from this study is that Australian institutions have varying capacities to deal with MTAs promptly and efficiently, based on resourcing issues but also organisational makeup and levels of delegation. The study therefore reveals some enlightening and generalisable

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<sup>2</sup> 'Material Transfer Agreements', *AUTM* (Web Page, 2019) <<https://autm.net/surveys-and-tools/agreements/material-transfer-agreements>>.

<sup>3</sup> Tania Bubela, Jenilee Guebert and Amrita Mishra, 'Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories and Litigation' (2015) 13(2) *PLoS Biology* 1002060:1-12.

<sup>4</sup> Jane Nielsen et al, 'My Way or the MTA: The Use of Material Transfer Agreements in Publicly Funded Research in Australia' (Occasional Paper No 10, Centre for Law and Genetics, 2018) ('My Way or the MTA').

data about technology transfer involving MTAs, and suggests that streamlining institutional processes within the technology transfer environment is key to facilitating ease of transfer.

## 2 Context

MTAs have failed to have an unreservedly positive effect on scientific research. Anecdotal evidence emerging during the late 1990s and early 2000s hinted that transfers of tangible research materials were potentially posing more problems for scientific advancement than hold-ups involving patents.<sup>5</sup> Delays resulting from the time taken to negotiate MTAs were identified as a major problem.<sup>6</sup> An early survey conducted by Henry et al<sup>7</sup> reported that because MTAs usually protect 'non-valuable' materials, they generally proceed with less negotiation, and correspondingly take less time than more complex agreements such as patent licences.<sup>8</sup> Subsequent studies are at odds with this finding.

A number of scholars have conducted empirical studies supporting the notion that the use of MTAs can cause hold-ups in biomedical research. Some studies implicate TTOs in universities and research institutes, with obstructionist practices in those offices responsible for delays in, and impediments to research. Key findings from empirical studies are outlined in Table 1, categorised according to whether the particular study contributed evidence of: hold-ups caused by withholding materials; delay in receiving materials; TTO involvement; and the specific problematic terms.

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<sup>5</sup> Cf David Blumenthal et al, 'Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty' (1997) 277(15) *Journal of the American Medical Association* 1224; Eric G Campbell et al, 'Data Withholding in Academic Genetics: Evidence from a National Survey' (2002) 287(4) *Journal of the American Medical Association* 473.

<sup>6</sup> Rebecca S Eisenberg, 'Bargaining over the Transfer of Research Tools: Is This Market Failing or Emerging?' in Rochelle Cooper Dreyfuss, Diane Leenheer Zimmerman and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford University Press, 2001) 223.

<sup>7</sup> Michelle R Henry et al, 'A Pilot Survey on the Licensing of DNA Inventions' (2003) 31(3) *Journal of Law, Medicine and Ethics* 442.

<sup>8</sup> *Ibid* 446.

Table 1: Empirical studies identifying sticking points/negative implications associated with MTAs

Study	Withholding	Delay	TTO Involvement	Particular Terms
<b>Eisenberg (2001)<sup>9</sup></b>		Time taken to negotiate MTAs a major problem		
<b>Campbell et al (2002)<sup>10</sup></b>	35% of researchers had a request for materials denied			
<b>Streitz and Bennett (2003)<sup>11</sup></b>		General finding that exchanges of tangible materials prone to cause delays to scientific advancement		
<b>Vogeli et al (2006)<sup>12</sup></b>	1/4 of doctoral and postdoctoral researchers had request denied			
<b>Monotti (2006)<sup>13</sup></b>		General finding that a significant number of respondents considered delays in obtaining materials to be their main source of		

<sup>9</sup> Eisenberg (n 6).

<sup>10</sup> Campbell et al (n 5).

<sup>11</sup> Wendy D Streitz and Alan B Bennett, 'Material Transfer Agreements: A University Perspective' (2003) 133(1) *Plant Physiology* 10.

<sup>12</sup> Christine Vogeli et al, 'Data Withholding and the Next Generation of Scientists: Results of a National Survey' (2006) 81(2) *Academic Medicine* 128.

<sup>13</sup> Ann L Monotti, 'Access to Tangible Research Materials in Biomedical Research: Conditions of Access and Their Effect on Research' (2006) 14 *Journal of Law and Medicine* 86.

		frustration/ main adverse effect <sup>14</sup>		
<b>Walsh, Cohen and Cho (2007)<sup>15</sup></b>	<p>19% of respondents had MTA requests from an academic researcher refused:</p> <ul style="list-style-type: none"> <li>• 33% of requests to industry researchers were not fulfilled</li> <li>• &gt;8% respondents reported a (usually temporary) cessation in research project because they could not access a material</li> </ul> <p>20% of respondents had most recent request</p>	<p>11% of requests for materials resulted in a delay of &gt;1 month<sup>16</sup></p> <p>Where MTA accompanied transfer:</p> <ul style="list-style-type: none"> <li>• Negotiations required in 40% of cases</li> <li>• 26% required significant negotiation of MTA terms, or negotiation lasting &gt; 1 month</li> </ul>	<p>61% of respondents requesting materials did not involve their institutional TTO</p> <p>Respondents more likely to do so where industry involved or other party attempted to impose terms that might be considered to be problematic</p> <p>Where TTO involved, refusal more likely and delay significantly more likely</p>	<p>Demands for reach-through rights to IP over future inventions and publication restrictions were commonly made, particularly from industry providers but also from university providers</p>

<sup>14</sup> Monotti seems to infer many respondents answered in this way due to MTA-related delays, although there was no specific question on whether this was due to MTA negotiations: see *ibid* 96–9.

<sup>15</sup> John P Walsh, Wesley M Cohen and Charlene Cho, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research' (2007) 36(8) *Research Policy* 1184 ('Where Excludability Matters'). See also John P Walsh, Charlene Cho and Wesley M Cohen, 'View from the Bench: Patents and Material Transfers' (2005) 309(5743) *Science* 2002.

<sup>16</sup> The requirement to enter into an MTA was not the only reason delays were encountered; only 42% of responses to requests were accompanied by a requirement to enter into an MTA: Walsh, Cohen and Cho, 'Where Excludability Matters' (n 15) 1193. More disagreement was likely to be encountered where a transfer was not accompanied by an MTA, which seemed to indicate there would have been reluctance to transfer these particular materials in any event.

	for a material refused			
<b>Hansen, Kisielewki and Asher (2007)<sup>17</sup></b>		<p>Settlement times for MTAs (whether involving patented technologies or not) were significant:</p> <ul style="list-style-type: none"> <li>• 40% took 2–6 months to complete</li> <li>• 32% occurred within 1–2 months</li> <li>• Transfers between academics: 46% took 1–2 months</li> <li>• Transfers from industry to academic: 48% took 2–6 months</li> </ul>		
<b>Mishra et al (2015)<sup>18</sup></b>		<p>Transfers of model mice through international consortia as problematic when dealing with research-focused academic institutions as between industry</p> <p>Delays of 6–18 months not uncommon</p>	<p>Respondents held TTOs responsible</p> <p>TTOs blamed a tendency on the part of particular TTOs to alter terms of standard agreements</p>	<p>Primarily due to demands for reach-through rights and high transaction costs</p>

<sup>17</sup> Stephen A Hansen, Michael R Kisielewski and Jana L Asher, *Intellectual Property Experiences in the United States Scientific Community* (Report, Project on Science and Intellectual Property in the Public Interest, American Association for the Advancement of Science, 2007).

<sup>18</sup> A Mishra, PN Schofield and T Bubela, 'Sustaining Large-Scale Infrastructure to Promote Pre-Competitive Biomedical Research: Lessons From Mouse Genomics' (2015) 33(2) *New Biotechnology* 280.

A series of studies<sup>19</sup> confirmed that exchanges of tangible materials are prone to cause delays to scientific advancement. They showed that outright denial of access or unnecessarily protracted negotiations could be particularly problematic: refusals to provide materials for research use are likely to be one of the more serious impediments to the biomedical research effort, should they lead to project abandonment. The study by Mishra et al<sup>20</sup> concerned use of MTAs by international mouse consortia and it was found that although negotiations with industry parties were particularly problematic, academic institutions were similarly difficult to deal with. Researchers saw TTOs as the culprits for delaying negotiations and research.

Walsh, Cohen and Cho also explored the impact of TTO involvement in the MTA negotiation process.<sup>21</sup> Their findings indicated that scientists engaged their TTOs where there was an industry partner or otherwise complicated MTA. Transactions involving TTOs were more likely to involve refusals or delays. As they acknowledged, this may reflect the fact that TTO officers see more complicated transfers. Alternatively, it might be possible to surmise that TTO officers are implicated in these delays.

The majority of studies reported here involved United States ('US') universities and institutes, although one Australian study involving a domestic university reported results that were consistent with the US studies.<sup>22</sup> Although these studies have contributed important findings on whether the use of MTAs hinders the transfer of materials, they have offered limited insight into what it is about the MTA process that creates inefficiencies. This study attempts to bridge that gap by examining the characteristics of institutional material transfer processes, and how these characteristics might fuel a culture of delay.

There has been considerable speculation as to why MTAs might generate delays, potentially stifling the open movement of biological research materials and hindering the development of an open research commons.<sup>23</sup> Some scholars have offered possible explanations for this trend. As a starting point, it is important to recognise that the exchange of materials can be problematic even without an MTA, as illustrated by Walsh, Cohen and Cho.<sup>24</sup> Difficulties tracking use of materials and greater competition between institutions for public and industry

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<sup>19</sup> Ibid; Streit and Bennett (n 11); Bubela, Guebert and Mishra (n 3).

<sup>20</sup> Mishra, Schofield and Bubela (n 18).

<sup>21</sup> See Walsh, Cohen and Cho, 'Where Excludability Matters' (n 15).

<sup>22</sup> Monotti (n 13).

<sup>23</sup> Charlotte Hess and Elinor Ostrom, 'Introduction: An Overview of the Knowledge Commons' in Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press, 2006) 3.

<sup>24</sup> Walsh, Cohen and Cho, 'Where Excludability Matters' (n 15) 1191-2.

funding might feed into decisions to resist sharing materials.<sup>25</sup> This funding environment might diminish the 'cooperative character' of research and related efficiency mechanisms,<sup>26</sup> and fuel risk averse behaviour. Increased commercial activity by research-focused institutions might also be a relevant factor.<sup>27</sup>

What role, then, do MTAs play in slowing down the pace of exchange and, by implication, the pace of research? There is evidence that MTAs promote the exchange of materials and the development of an open research commons.<sup>28</sup>

Indeed, Walsh et al found that scientists who are prepared to sign MTAs are more likely to receive requested materials.<sup>29</sup> But at what point do MTAs generate more problems than they solve? The evidence presented above demonstrates that delays are seemingly inevitable once MTA processes are engaged. Can these delays be attributed not simply to the incorporation of MTAs into the transfer process, but to inefficiencies in the way in which the MTA process is conducted?

There is undoubtedly a culture of risk aversion on the part of many institutional administrators.<sup>30</sup> As a consequence, they tend to want to account for every eventuality that may arise in the future during the process of negotiating MTAs.<sup>31</sup> Such eventualities might include concerns relating to:

- safety of the material, including issues of liability and appropriate use;
- legal risks including inappropriate use, or use that infringes the intellectual property of third parties;
- reputational risks, leading negotiators to require protection of rights to be acknowledged or attributed, or rights to publish; and

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<sup>25</sup> Ibid; Campbell et al (n 5).

<sup>26</sup> Wesley M Cohen and John P Walsh, 'Real Impediments to Academic Biomedical Research' in Adam B Jaffe, Josh Lerner and Scott Stern (eds), *Innovation Policy and Economy* (University of Chicago Press, 2008) vol 8, 1, 20.

<sup>27</sup> Walsh, Cohen and Cho, 'Where Excludability Matters' (n 15) 1196-7.

<sup>28</sup> Thinh Nguyen, 'Case 6: The Science Commons Material Transfer Agreement Project' in Geertrui Van Overwalle (ed.), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge University Press, 2009).

<sup>29</sup> Walsh, Cohen and Cho, 'Where Excludability Matters' (n 15) 1195.

<sup>30</sup> Jane Nielsen et al, 'Provenance and Risk in Transfer of Biological Materials' (2018) 16(8) *PLoS Biology* 2006031:1-9 ('Provenance and Risk').

<sup>31</sup> Bubela, Guebert and Mishra (n 3).

- loss of control of future intellectual property and subsequent loss of opportunity to share in revenue from commercial exploitation.<sup>32</sup>

These factors, or possibly a combination of them, create a real possibility that institutions will engage in risk averse behaviour by attempting to impose terms aimed at mitigating risk, or capturing downstream benefit.

The importance placed on these perceived risks and benefits has led to the dedication of resources to personnel involved in transfer of materials, and to increased bureaucratisation of the transfer process.<sup>33</sup> This, in turn, sets up an important precondition for disputes and delays during the exchange process. Although parties might be more willing to hand over materials with an MTA in place, insistence by either party on the inclusion of restrictive terms in MTAs can result in an unwillingness to proceed with the exchange.<sup>34</sup>

### 3 Methods

Our study involved investigation of the role of MTAs in predominantly biological or biomedical exchanges of materials involving universities and research institutes in Australia. Australia has a rich tradition of biomedical research, particularly research emanating from public funding.<sup>35</sup> There were 43 accredited universities, some of which are engaged in very limited amounts of research, but many of which are highly research active. A number of research institutes are also engaged in health and medical research, some of which are associated with universities. This study was undertaken in light of the exploration of these issues overseas, and because it is likely that the number of MTAs in circulation has proliferated in Australia, as it has elsewhere.

#### 3.1 Interviews with TTOs

One of the components of this mixed-methods study involved semi-structured interviews with personnel from TTOs in universities and research institutes in Australia. In total, 40 interviews were conducted, usually by telephone, with representatives from 25 universities and seven research institutes. In the case of five institutions, we conducted more than one interview in order to obtain either a complete picture of material transfers within those institutions, or a clearer

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<sup>32</sup> Nielsen et al, 'Provenance and Risk' (n 30).

<sup>33</sup> Brady Huggett, 'Reinventing Tech Transfer: US University Technology Transfer Offices are Adopting New Models in Search of Increased Return on Research Investment' (2014) 32(12) *Nature Biotechnology* 1184; David C Mowery and Arvids A Ziedinis, 'Academic Patents and Materials Transfer Agreements: Substitutes or Complements?' (2007) 32(3) *Journal of Technology Transfer* 157; Eisenberg (n 6).

<sup>34</sup> Cohen and Walsh (n 26).

<sup>35</sup> Warwick Anderson, 'Healthy, Wealthy and Affordable' (Derrick-Mackerras Lecture, QIMR Berghofer Medical Research Institute, 21 October 2014).

picture of biological material transfers. All universities implemented MTAs for biological or biomedical-related research, and for all but two of the 25 universities, this was their predominant area of transfer. If there were personnel in charge of different types of transfers, we spoke to those dealing predominantly with biological and medical-research transfers. In some cases, more than one representative from an organisation was present. In total, we interviewed 42 personnel involved in the transfer of materials between universities, research institutes, and commercial entities. A number also transferred materials from intermediary distributors such as Addgene and the Jackson Laboratory.

Participants were selected using purposive and critical case sampling techniques. Our reviews of existing literature and previous studies provided an invaluable backdrop against which to construct an effective conceptual framework for iterative data analysis. Employing nVivo software, transcripts were coded and analysed inductively using thematic and latent content analysis techniques,<sup>36</sup> with findings from interviews being progressively used to inform subsequent interviews.

We recognise there are limitations in this particular methodology that relate primarily to the sample size. Even so, our sample captured a significant proportion of Australian universities and major research institutes involved in biomedical research. A limitation of the university-TTO surveys is that some interviewees commented on all MTAs, regardless of whether they were biological/biomedical. For the two cases mentioned above, the main materials transferred were in the agricultural, plant-based or environmental areas. Three other interviewees indicated that up to half of the transfers conducted involved materials that were not biological. These universities all executed 50 or fewer MTAs per year (one conducted less than 10, one conducted between 11–20 and the remaining three conducted between 21–30).

The subjective selection of themes and evidence to support our findings is also acknowledged, although findings were validated using accepted practices, and interviews were conducted to thematic saturation. The benefit of conducting semi-structured interviews is that it permitted in-depth exploration as to whether difficulties (including refusals to supply materials and delays) might be occurring, as well as the grounds for such difficulties. Qualitative evidence lends itself to inductive formation of concepts as opposed to generalisable hypotheses.<sup>37</sup>

### 3.2 Survey of Biomedical Researchers

A survey was developed to examine the experience and attitudes of Australian biomedical researchers with regard to transfers of materials. The survey was

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<sup>36</sup> Maria J Mayan, *Essentials of Qualitative Inquiry* (Left Coast Press, 2009).

<sup>37</sup> Jane Richie et al, 'Designing and Selecting Samples' in Jane Richie et al (eds), *Qualitative Research Practice: A Guide for Social Science Students and Researchers* (Sage Publications, 2<sup>nd</sup> ed, 2014).

delivered on Survey Monkey. The survey asked a series of initial questions about the research profile of the scientist and their institution. It then asked a series of questions designed to ascertain the degree to which scientists were transferring materials subject to MTAs, both incoming and outgoing. Finally, a number of questions asked respondents about difficulties they may have encountered in relation to the use of MTAs when transferring materials.

Respondents were selected using the Scopus publications database. Searches identified researchers based on their research publications for 2014, and their affiliation with Australian universities and research institutions. Searches of publications using the terms 'Australia', 'genetics', 'human' and 'not agriculture' were conducted, and researchers' names were collected based on their listing as first, second or last authors on publications. Searches were conducted until the names of 900 researchers who met the search criteria had been collated. Some names were excluded because contact details could not be obtained, and recurring names were removed from the list.

Emails were sent on 18 August 2016 to all researchers on the list, directing them to the survey on Survey Monkey and asking them to respond. A reminder was sent on 5 September 2016. 39 emails were returned and 330 remained unopened. 496 emails were opened and 128 respondents clicked through the survey (14.4%). A total of 122 complete (111) or partial (11) responses were received. Although low, the response rate is not atypical when compared with other surveys in the biomedical field. 109 survey respondents self-identified their affiliations as follows:

Table 2: Survey respondent profile

Respondent Type	Unive-rsity	Research Institute	Hospital	Clinical Rooms	Other	Dual <sup>38</sup>	Total
Number	23	68	2	1	3	10	109

### 3.3 Interviews with Biomedical Researchers

A small number of interviews (seven) were conducted with biomedical researchers to confirm and supplement the survey findings. These interviews were conducted using a similar methodology to that described in relation to the TTO interviews.

<sup>38</sup> Respondents were permitted to select more than one research environment. As such, some respondents were classified as having a dual classification.

## 4 *Results and Discussion*

### 4.1 *Survey of Biomedical Researchers*

Many of the biomedical researchers who responded to the survey had suffered adverse effects from MTAs in the last 12 months (48%). Of those, 97% of respondents said the nature of the adverse effect included delay. Eight percent reported a cessation of research.

Despite these concerns, 69% of respondents indicated that they considered MTAs to be 'very beneficial' or 'somewhat beneficial' when supplying materials. 61% of respondents answered in this way in respect of receiving materials. These results thus appear to clearly indicate that MTAs are generally viewed as having positive impact despite the fact they frequently delay research. The results are interesting because they are markedly similar whether respondents are engaged in receiving or supplying materials. This may reflect the fact that respondents answered both questions in a similar way. It may also hint at acceptance of MTAs as part of the business of exchanging materials, coupled with a certain degree of frustration with institutional processes driving transfers. Comments received in respect of both these questions reinforce this. Even those respondents who commented in respect of receiving materials that they 'should be beneficial', or that they are 'useful' or 'helpful' often tempered their comments:

Sometimes MTAs are useful, but I have never had any problems with suppliers or the downstream use of material, and more often than not the MTA is an administrative step that slows down the process of obtaining the material.

There are two types of MTA – some materials have significant ethical, commercial and scientific issues that need clarification – MTAs are essential. The other group are all the reagents for which that MTA has no commercial or scientific consequences. These are a massive waste of time and clarify/protect nothing.

Takes months, lots of lawyers and prevents the research proceeding. Australian environment is now so lawyer rich and risk averse that research is being crippled over trivial issues.

MTAs are helpful to clarify, but they take so long to negotiate (even when no negotiating should be done) that they impede rapid progress.

Comments received from those supplying materials were markedly similar:

MTAs have a place where obvious [intellectual property] or real risk to human rights, safety or confidentiality are obvious. But should not be the default. They are way overused. Where the risks are minimal or close to zero, they should not be necessary. A massive amount of research time and opportunity is lost for very dubious benefit overall. One must take into account the costs of staff (business and legal), costs on research and the opportunity cost to progress. If patient advocates knew they would be very unhappy.

Of the hundreds of MTA based transfers I have been involved in, I have not once found them to be useful. They cause delays, generate unnecessary paperwork and generally hinder research.

MTAs are useful because they clarify the terms of transfer but they often take so much time to negotiate that the resulting delays in research are difficult in 3 year funding cycles.

Given the relative breadth of the survey respondent affiliation profile, it is clear that many of these respondents are experienced in the use of transfers involving MTAs. This lends weight to the theory that although researchers accept MTAs as an inevitable part of the business of material transfer, they consider the bureaucratic delays that accompany MTAs to be frustrating and unnecessary. We were not able to glean what an 'unacceptable' delay means for survey respondents. However, our interviews with scientists provide some limited insight into this issue.

## **4.2 Interviews with Biomedical Researchers**

Of the researchers interviewed, one commented that MTAs were universally processed by their Business Development Office quickly – generally within the working week. Another reported fairly straightforward MTA processes involving sign-off by the research group involved in transfers. This researcher said that MTAs were only really slowed down if the material involved was 'sensitive' (such as a transgenic animal as opposed to a plasmid or DNA). Under these circumstances, slower negotiations were tolerated. All of the other interviewees had encountered delays of some description that caused them frustration. One commented that 50% of transactions progress very smoothly and are completed within a week, 30% are 'pretty smooth' and 20% are problematic. The average turnaround time for this interviewee was four weeks, which 'you can cope with'. But some had been known to take 'months and months'. Another interviewee stated that their Business Development Office was really supportive in getting agreements in place, but that sometimes there were really annoying delays (including one that had taken more than a year).

The remaining interviewees were generally positive about MTAs but negative about the processes accompanying them. One interviewee said that the 'really fast' MTAs take about two weeks, but most can sit in in-trays for weeks on end. It really 'depends on the person you contact in the relevant area of the [university]'. Another interviewee who is involved in around 30–50 MTAs per year, all of which go through their legal department, commented that she spends a lot of time chasing up MTAs to make sure things have not got stuck somewhere along the path. Simpler MTAs can be quick, but one took 18 months. Finally, one interviewee stated that their standard MTA template never seemed to be applicable for one reason or another, requiring tweaks by their legal contracts department that delayed negotiations. This interviewee said that international MTAs take months, while even local transfers often take at least a month. She

estimated the average for outgoing transfers to be eight or nine weeks, usually due to delays by the recipient organisation.

### **4.3 Overview of TTO Interview Findings**

Results taken from our TTO interviews are summarised in Table 3. They reveal an established culture of materials exchange within and between universities and research institutes in Australia. Our results demonstrate considerable variance between institutions in relation to the volume of transactions undertaken. Numbers are based on interviewees' best estimates as to the annual volume of transactions undertaken. A number of universities, in particular, executed very few MTAs, with ten executing less than 20 per annum. In contrast, every research institute executed at least 30 MTAs per year.

A vast majority of university-based TTO interviewees indicated that they transfer more materials into their institutions than out. In fact, very few execute a significant number of outgoing MTAs. Only two university interviewees indicated that they transferred out more than a few materials per year: one university interviewee falling into the 30–50 MTAs per year category said that just under half of their transactions involved outgoing materials. Another university interviewee falling within the 300+ category stated that around one third of MTAs executed per year involved outgoing materials. In contrast, all of the seven research institutes transferred considerable numbers of materials out.

Given the preponderance of incoming MTAs in the university sector, it might be expected that delays caused by MTA negotiations would be minimal, on the basis that most suppliers of materials will insist on using their own MTA. If every party receiving a material was willing to use the supplier's MTA there is every reason to believe the result would be a streamlining of processes. However, the evidence points to time frames for execution of anything from 1–2 days to 'months'. This suggests that institutions (generally universities) exhibit a high degree of caution when conducting MTA negotiations – it is probably the case that they often see new agreements, necessitating the need for review.

In generating and analysing data, themes began to emerge. We used the number of MTAs entered into by an institution per year as a proxy to measure the extent to which levels of 'experience' in administering MTAs impacted on the efficiency with which they were executed.<sup>39</sup> We were particularly interested in exploring the factors associated with delay reported in previous studies. We anticipated continuing evidence of delay within Australian institutional transfers resulting from the MTA negotiation and execution process.

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<sup>39</sup> See Table 3.

#### **4.4 Levels of 'Experience' and Length of MTA Negotiations?**

Our results in relation to time taken to execute MTAs confirmed that greater experience with negotiating MTAs leads to reduced delays. Generally speaking, those institutions entering into larger numbers of MTAs had more streamlined procedures for negotiating them. As a rule, those institutions also managed sign-off on MTAs more rapidly. The critical point at which marked efficiencies are seen is where the number of transactions per year was at least 21. Institutions undertaking less than 20 transactions per year indicated that, on the whole, they had more transactions tending toward the longer time periods they had provided. For example, of the six institutions who had 10 transactions per year or fewer, only one estimated that MTAs might take as little as seven to 10 days to sign-off. Even for this interviewee this was unusually quick, and the process was ordinarily in the order of one month. The remainder reported that MTAs usually took considerably longer: between two and four weeks for two interviewees but at least a month for the other three.

For institutions conducting in excess of 301 MTAs per year, interviewees indicated that a vast majority could be executed within a day. Although some (opposing) parties slowed the process down by wanting to negotiate terms, this was something these interviewees tried to avoid: as one interviewee put it, researchers cannot afford a delay lasting months in a three-year research program. This interviewee attributed a desire to negotiate on the part of other parties, despite the low likelihood of commercial prospects, to '... some of it [being] inexperience but some of it [is] a cultural thing.' This points to inexperience being one underlying factor in delays in MTA negotiations.

#### **4.5 What Constitutes 'Delay' in Negotiations?**

The TTO interviews suggest that delays in MTA negotiations involving Australian universities and research-focused institutions are not overly protracted in that the 'average' time from request to sign-off is around two weeks. We have no reason to believe that interviewees under-estimated the time taken to conclude MTAs. Although some isolated negotiations become drawn out, these instances are relatively unusual and a majority of transactions were described as fairly straightforward. Given this, it is perhaps surprising that simple transactions can take as long as two weeks to conclude.

Admittedly, a number of interviewees did provide evidence that some transactions were concluded very quickly ('instant' to 'one or two days'). These often involved requests for materials from non-profit intermediaries such as Addgene and the Jackson Laboratories.

Table 3: Processes to MTA sign-off by level of institutional MTA activity

<b>Number of MTAs/year*</b>									
<b>Number of Institutions</b>	6	4	4	5	4	5	4	3	301+
<b>Average time taken to sign-off</b>	7 days to 'months'	Couple of days (1) to 3 months	1 - 2 days to 2 weeks	1 - 2 days to several weeks	'Instant' to 2 weeks	1-2 days to 2 weeks	1-2 days to 1 month	1-2 days to a couple of months	
<b>Delegated sign-off</b>	VC, DVC, PVC, Company Secretary	DVC, PVC, Industry Engagement Officer	DVC, Research Office	DVC, Office of Innovation, TTO Office, COO	Director of Research, Commercialisation or Legal	HOS or Department, Director or Deputy Director of Faculty Office, Head of Business Development, TTO Officer	Commercialisation unit staff, Head of Business Development, IP and Contracts officer, Research program director		

<p><b>Path to sign-off</b></p>	<p>No defined path or multiple parties involved</p>	<p>Multiple parties involved</p>	<p>Usually through research or commercialisation offices, then legal</p>	<p>Research or commercialisation offices. Often different pathway depending on whether simple or complex (legal will review)</p>	<p>Research or commercialisation offices. Often different pathway depending on whether simple or complex (legal will review)</p>	<p>Dealt with by TTOs, either located in Faculties or university-wide. Legal review if very complex</p>	<p>Commercialisation unit or research office. Delegated sign-off at lower level</p>	<p><b>Main purpose of MTAs</b></p>	<p>Protection, indemnification, intellectual property, clarification, publication</p>	<p>Decrease risk, protection, indemnification, clarification, intellectual property</p>	<p>Protection, control, provenance, intellectual property, clarification, publication, collaboration</p>	<p>Certainty, provenance, decrease risk, indemnification, publication</p>	<p>Certainty, indemnification, protection, intellectual property, publication</p>	<p>Certainty, decrease risk, boundaries, clarification, provenance, intellectual property, indemnification</p>	<p>Provenance, collaboration, legal certainty, publication, decrease risks, less about protecting value</p>
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These requests for materials were concluded quickly because intermediaries require execution of a standard contract. The removal of choice from contract negotiations had a positive effect in that it expedited the transfer process.<sup>40</sup> It is also important to remember that the transfer of materials from these intermediaries were only for research purposes: generally, these uses were seen to be uncontentious and parties were content to accept the terms on which intermediaries insisted. However, it became clear that transactions involving other institutions or commercial parties usually took far longer. The key to overcoming this may lie in educating institutional officers as to the low prospects of commercial outcomes. Where transfers take place for research purposes (as they do in a majority of cases), complex negotiations seeking particular outcomes in relation to intellectual property and other commercial matters are generally redundant.<sup>41</sup>

As previously noted, those institutions with smaller workflows of MTAs tended to take longer, on average, to conclude negotiations. A relevant factor is that TTO officers in these categories tended to view transactions with these parties as requiring tailored agreement, primarily to protect their institution. On the whole, interviewees who entered into 21–30 or fewer transactions per year were less likely to indicate that MTAs took a day or two to conclude. More commonly, negotiations in which they were involved took at least two weeks. Some of the interviewees in categories with a lower volume of transactions acknowledged that the time frames they were dealing with were problematic, with one accepting that a two to three month negotiating period could be frustrating for researchers. Another stated that sign-off could be achieved within three weeks if negotiations were very focused, but would otherwise be longer. One explicitly recognised the understandable concern of researchers about these delays:

I am personally lucky because these researchers and I have established a good relationship because I have been here at the University for quite a while now. But I do share their frustrations and I understand. ... I'm sorry to say this but in terms of priorities, MTAs are not something we attach a high priority to.

However, other interviewees in these 'lower' categories felt longer time periods for negotiating MTAs were entirely reasonable. When asked the average time between receiving a request to execute an MTA and signing-off, one interviewee answered:

Not very long usually. We have a bit more of a longer signing process with the international agreements and that has a tendency to throw out all our agreements a little bit. But if we're using our template then that's quite quick ... I would hope a month. That's with scanned copies of the agreement.

Table 3 clearly shows that as the volume of MTA transactions conducted by interviewees increased, the average period of time taken to negotiate MTAs

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<sup>40</sup> Nielsen et al, 'Provenance and Risk' (n 30).

<sup>41</sup> Ibid.

decreased. More complex negotiations generally took at least two weeks to conclude, but only two interviewees who conduct 31 MTAs or more per year (both falling within the 31–50 category) provide two weeks as the minimum period of time necessary to conduct MTA negotiations (encompassing sign-off by both parties). Every other interviewee falling within these categories at the higher end of the scale stated that many transactions involve a very quick turnaround time of one to several days. Notably, most of these institutions transferred materials in, as well as out, indicating that they probably accept the MTAs provided by suppliers fairly regularly. Non-standard MTAs do, however, generally take longer to finalise:

If they are non-standard the normal turnaround time would be ten working days ... That is a bit dependent on factors like workload of legal department, availability of the scientists of both sides, legal department on the other side, time difference and these typical things.

Despite this, another interviewee indicated that his specialist unit took 'a day or two' even if the MTA was required to be reviewed by his university's legal team. This, of course, does not tell the whole story on time taken to execution as it does not incorporate sign-off by both parties.

In contrast with US studies, our results indicate that although MTAs are used relatively frequently, negotiations lasting more than a month are uncommon. Although some outliers might take 'a couple of months' or in one case, 'one and a half years', it was clear that these are exceptional cases. A resounding comment from many interviewees was that the time taken to negotiate MTAs is variable, and largely depends on the willingness of the party with whom they are negotiating to conclude a negotiation quickly. This proved a source of frustration for many.

#### **4.6 Institutional Processes and Impact on Negotiation Times**

Despite the fact MTAs are becoming commonplace, structures through which they pass in different institutions are far from uniform. Our data demonstrates that while most institutions have a TTO or at least a designated technology transfer officer or equivalent, the scope of TTO responsibility varies considerably. Interviewees from a number of universities reported having one person responsible for MTAs. Others dealing with a greater volume of transactions often had several dedicated staff. The level of responsibility for execution of MTAs varies. Institutions executing fewer MTAs were far more likely to require sign-off by a senior executive such as the Vice Chancellor, Deputy Vice Chancellor-Research or other senior executive member.

A distinct trend was evident within institutions with higher levels of MTA activity for the sign-off process to be expedited, generally through delegation to heads of school, or directors of faculties or research programs. As one interviewee whose university engages in over 300 MTA transactions per year observed:

[I]n terms of legal sign-off our senior business development managers and senior management like myself have delegated sign-off, so they'll be negotiated typically by one of our associate level staff with ... a couple of years' experience, but if they've got any issues they'll come to one of the senior people. ... To be honest, for outgoing ones there are very few issues that are significant, it's more for the incoming ones where we come across some issues.

Another university TTO officer whose university deals with around 40 MTAs per year commented that:

[S]ign-off for MTAs technically comes through to the DVCR but she delegates that to the Deans of the Colleges ... actually we're just looking at those delegations because we think they might [still] be at too high a level.

This particular interviewee, as head of his university's TTO, felt that it was more efficient if he did not see every MTA:

[Given] the volume of MTAs and their increasing volume and the standardisation of practice, providing we can put the stage gate in and that it's reviewed by someone that knows what to do then who signs it is of less importance ...

A clear correlation was observed between delegated sign-off procedures and decreased sign-off time. In addition, institutional administrative structures with the highest level of efficiency (in terms of MTA turnaround time), were those that had simplified the process of materials transfer. Although formal agreements were still put in place, the processes for communicating with scientists, negotiating, and signing-off on MTAs was significantly more straightforward than in institutions where a more protracted process was in place. More meticulous processes were reserved for complex transactions,<sup>42</sup> whereby legal personnel often became involved.

#### **4.7 Purpose Behind MTAs**

All TTO interviewees were asked what they considered to be the main purpose(s) of MTAs. The answers provide some insights into why MTAs might be subject to more convoluted procedures in some institutions than others. It is possible to discern subtle differences in the language used to describe the purpose of MTAs: the purpose ascribed to MTAs differed somewhat depending on the volume of MTAs transacted by institutions.

The level of institutional MTA activity also had an effect on the language used to describe the purpose of MTAs. For institutions with the highest levels of MTA activity, interviewees more commonly described the purpose of MTAs as being facilitative – to increase certainty and record provenance, to foster collaboration and to clarify the terms of the exchange. For example, an interviewee from one university commented:

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<sup>42</sup> See also *ibid.*

It is really just to keep the research effort in locomotion. That is what it seems to me in a general sense. They really do facilitate, or just add a bit of comfort to the relationship, especially where you do not know the other party. So it just provides a level of comfort and on it goes.

In respect of those institutions that conducted fewer MTA negotiations, interviewees tended to use terms such as 'protection', 'indemnification' and 'control of intellectual property' far more frequently. But many terms were commonly used across all categories (examples include 'clarification', 'decrease risk', and 'publication'). The perceived importance of protection of intellectual property as a basis for MTAs was not exclusive to interviewees engaging in fewer transactions. However, interviewees from institutions undertaking fewer transactions had a greater tendency to articulate intellectual property concerns. It was frequently cited by interviewees in these categories as the primary purpose for using MTAs. One interviewee whose university conducts in the vicinity of 11-20 MTAs per year stated that an MTA:

Is really to lock down intellectual property, or your original thought that's gone into development of the technology. So, if you have provided a lot of time and effort and creative ability into creating the technology then you would want to have some security. If you collaborate or give it away that it will be properly acknowledged and if money is to be made from it then you want some sort of reward for your efforts.

There was also a correlation between turnaround time and views on the purpose of MTAs. Interviewees from institutions with more efficient turnaround times more commonly used terms such as 'maintaining integrity of title', 'formalisation', 'acknowledgement' or 'recognition' and 'collaboration'. A number of interviewees who had estimated longer turnaround times were at pains to emphasise that 'locking down intellectual property' was a fundamental basis for formal MTAs. A similar trend was evident if terms connoting purpose are examined in light of institutional structures. There is a clear link between volume of transactions, institutional processes and path to sign-off.

Many interviewees whose institutions fell within the category of the highest number of transactions (and, on average, the shortest turnaround times), explicitly pointed out that MTAs are rarely, if ever about protecting intellectual property. They were also realistic about the prospect of a commercial outcome from research and, accordingly, preferred that provision be made for dealing with intellectual property only if and when it became an issue. Responses from these interviewees were typified by one respondent's comment that the chance of a commercial outcome is 'one in a million'.

The correlation between high volume of transactions, efficiency in institutional structures, fast turnaround times and recognition that MTAs are rarely useful for protecting commercial outcomes of the use of materials, provides a basis for concluding that these interviewees are less likely to become caught up in arguing over contentious terms in MTAs.

#### 4.8 The Evidence from TTOs on Specific MTA Holdups

Our evidence appears to indicate that the typical time taken to negotiate and sign-off on MTAs varies widely, and ranges from one or two days, to 'months'. Involvement in a greater volume of transactions seems to equate with more efficiency in signing-off on MTAs. We sought specific evidence on this question, and asked TTO interviewees what they had encountered in terms of 'sticking points' in MTA negotiations. Results from this series of questions are represented in Table 4.

*Table 4: Identification of 'sticking points' from negotiation to execution by level of institutional MTA activity*

Number of MTAs/year	Less than 10	11-20	21-30	31-50	51-100	101-300	301+	Total Number of Institutions
Number of institutions	6	4	5	4	5	4	3	31
Time/delay	4 (66%)	3 (75%)	1 (20%)	4 (100%)	3 (60%)	2 (50%)	2 (66%)	19 (61%)
Inflexibility	2 (33%)		2 (40%)	2 (50%)	4 (80%)	3 (75%)	1 (33%)	14 (45%)
Particular Parties	3 (50%)	2 (50%)	2 (40%)	3 (75%)	5 (100%)	3 (75%)	2 (66%)	20 (65%)
Overvaluation of material	1 (17%)	1 (25%)		1 (25%)		1 (25%)	1 (33%)	5 (16%)
Intellectual property	2 (33%)	2 (50%)	4 (80%)	2 (50%)	3 (60%)	3 (75%)	3 (100%)	19 (61%)
Indemnification		1 (25%)		2 (50%)	4 (80%)	4 (100%)		11 (35%)
Publication	2 (33%)	1 (25%)	2 (40%)	3 (75%)	4 (80%)	4 (100%)	1 (33%)	17 (55%)
Inexperience	2 (33%)	1 (25%)	2 (40%)	1 (25%)	1 (20%)			7 (23%)
Culture or individual	1 (17%)	3 (75%)	3 (60%)	4 (100%)	5 (100%)	4 (100%)	3 (100%)	23 (74%)
Jurisdiction: International MTAs	1 (17%)	1 (25%)	1 (20%)	2 (50%)	3 (60%)	2 (50%)		10 (32%)

As Table 4 illustrates, a large number of interviewees acknowledged delay was a negative aspect of MTA negotiations (61% of total interviewees). Interviewees who engaged in at least 31 transactions per year were more likely to view delays as an impediment in MTA transactions. This is not surprising given that their own processes were likely to be efficient, and delays on the part of other parties no doubt a source of frustration. The remaining questions interrogated the extent to which particular aspects of MTAs were 'sticking points' in negotiations, some of these invariably feeding into the delays complained of by interviewees.

Inexperience was cited as a problem less frequently than we might have anticipated (23% in total), and paradoxically, only by interviewees from institutions undertaking fewer transfers. While it may not be a major issue, it is almost certainly a factor playing out in negotiations. It was also likely accounted for in other comments made, particularly those relating to culture and the impact of individuals on MTA negotiations. Cultural idiosyncrasies and characteristics of particular individuals within organisations accounted for a great many perceived problems with MTA processes (74% across all groups of interviewees). This was the most common sticking point identified by interviewees, particularly those undertaking 51 or more transactions per year. It highlights the fact that negative perceptions of the MTA process are very much driven by individual characteristics and culture within institutions, and the lack of homogeneity this produces. At the upper end of the scale, inflexibility in conducting negotiations was also seen as challenging (45%), especially by those interviewees who conducted in excess of 51 transactions per year.

Sixty-five percent of interviewees considered that particular parties or groups of institutions (such as commercial parties or international institutions) presented problems. Respondents' views were very variable across categories of interviewees, although it is possible to discern some patterns. Table 5 captures the range of parties identified as presenting obstacles in some circumstances. It demonstrates that parties conducting fewer MTA transactions appear to have different views on particular parties as being problematic than those conducting higher numbers. Commercial parties were mentioned by interviewees in every group except those conducting 301 or more transactions per year. But commercial parties were mentioned less frequently by interviewees conducting 31 or more MTAs than those falling into lower volume categories. This 'higher' volume group is seemingly more accepting of the demands made by commercial parties, and many commented that while commercial parties have certain requirements, these are rarely an issue of concern. Of course, it may also be indicative of their greater bargaining power given that they are invariably more experienced negotiators.

Universities featured prominently in comments made by interviewees across all levels of transfer activity as constituting problematic negotiators. This reflects the fact that they are probably the group most frequently party to MTA transactions, and also reinforces the importance of institutional culture. International institutions, especially US universities were mentioned by a considerable number

of interviewees, on two main grounds. One is their insistence on the inclusion of terms requiring disputes to be resolved under the law of the state in which the institution is based (32% of interviewees mentioned this point). Generally, more 'experienced' interviewees indicated that this issue was not difficult to overcome and requests to leave the question of jurisdiction silent were often accepted. Another matter of concern in relation to US universities was their tendency to want to depart from the standard terms of the Uniform Biological Material Transfer Agreement ('UBMTA'),<sup>43</sup> with the result that every agreement needed to be carefully checked, as it could not be assumed that terms were uniform across agreements. Better resourced interviewees perceived this issue to be less problematic.<sup>44</sup>

Interviewees across the board considered the seeking of rights over intellectual property, derivatives and modifications to be sticking points, particularly those engaged in a higher volume of transactions (61% of total interviewees). This issue arose primarily in respect of transactions involving universities and research institutes. Although commercial rights were often sought by commercial parties this was accepted to some degree as part of the process of doing business with them. This is consistent with findings by Walsh, Cohen and Cho that the inclusion of terms seeking reach-through rights is not limited to commercial parties.<sup>45</sup> Publication, too, proved to be a sticking point for many, with a considerable number of interviewees expressing frustration at attempted restrictions on publication (55% in total).

Seeking indemnification for the use of materials was also a dominant issue for interviewees undertaking between 51 and 300 transactions per year, although it factored very little for interviewees in other categories. Comments by these interviewees indicated that they are forced to contend with risk averse parties (particularly within smaller universities) seeking indemnification despite the fact the risks from using particular materials are very low. Risk aversion remains a prominent feature of many MTA negotiations, particularly amongst parties with less efficient MTA processes and lower MTA volume.

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<sup>43</sup> 'Uniform Biological Material Transfer Agreement', *AUTM* (Web Page, 2019) <<https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement>>.

<sup>44</sup> See generally Nielsen et al, 'My Way or the MTA' (n 4).

<sup>45</sup> Walsh, Cohen and Cho, 'Where Excludability Matters' (n 15) 1193.

Table 5: Parties identified by TTOs as being problematic in MTA negotiations

Number of MTAs/year*	Less than 10	11-20	20-30	31-50	51-100	101-300	301+
Number of Institutions	6	4	5	4	5	4	3
Particular parties identified as being 'problematic' in MTA transactions	International institutions US universities 'Bigger' Australian universities Commercial parties Big pharma	Universities CSIRO Inexperienced parties Commercial parties Smaller companies	Universities Larger universities Biotechnology companies Big pharma	Big Australian universities Smaller Australian universities Certain Australian institutions Inexperienced parties US universities Big pharma	Universities Australian universities US universities EU universities Overseas institutions Commercial parties Small companies Large companies Big pharma	Universities Research institutes US institutions Individuals within institutions Companies US companies Big pharma	Australian institutions, universities and hospitals US universities French hospitals

## 5 Conclusion

With previous studies reporting significant delays in concluding MTA negotiations, unease by scientists about MTAs impeding research would appear to be well founded. Our results suggest that scientists remain concerned about the impact of delays, although the delays inherent in negotiating MTAs within the Australian public research community generally appear to fall well under the averages observed by those earlier studies. The average turnaround time reported in our TTO interviews is likely to be in the vicinity of two weeks.

This is not to say that some transactions do not take longer, however, it was the period of time most frequently cited as the 'average'. Many respondents experienced in material transfers commented that transactions often took a matter of days to complete.

At the same time, a large number of our TTO interviewees complained that delays on the part of other parties frequently delayed the MTA process. Common reasons for delay included insistence on terms claiming intellectual property rights and rights to derivatives and modifications, as well as terms attempting to control publications over results produced using particular materials. By far the most prevalent complaints, however, related to inefficiencies attributed to particular parties, and the cultural or idiosyncratic characteristics of the organisations concerned. There is no doubt that inefficiencies on the part of some parties, particularly institutions with more convoluted negotiation and sign-off processes, result in the slowing down of negotiations. Evidence that some transactions take in the vicinity of 'months' suggests that there are instances where unacceptable delays arise.

To some extent, there also appears to be a mismatch in some cases between what representatives from TTOs perceive to be a delay, and what scientists see as constituting a delay. Particularly where materials are being requested, scientists have research timelines that necessitate quick turnover. Given our small sample size, it is possible that we encountered a particular group of scientists who had experienced protracted transactions. Alternatively, it may suggest that isolated experiences where negotiations are delayed leads to frustration amongst researchers. The process may also be more frustrating for scientists transferring a greater number of materials, given the inevitable increase on their administrative burden.

Regardless, respondents from each group acknowledged that delays are part of MTA-life. Accepting that MTAs are (and should be) an inevitable component of the transfer of materials, we must ask how the process can be improved. A useful starting point would be to encourage institutions, both universities and research institutes, to strive for efficient structures and processes. Streamlining processes will include deployment of simplified agreements without deviating from their terms: given the relatively low success rate of standard agreements, messages promoting simple agreements with few terms are likely to be better received.

Other measures that might effectively enhance MTA practices include encouraging parties to be realistic about risk and benefit, minimising the need for duplication in review processes, delegating sign-off authority and consulting researchers during the process of MTA negotiation.<sup>46</sup> What is required in order to discourage deviation from simple (and standard) terms in MTAs is cultural shift. Supporting those involved in the administrative process of MTA negotiation on a policy level, to better understand the fundamental purpose of materials exchange (enabling research rather than profit generation), is key to achieving simplicity.

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<sup>46</sup> Nielsen et al, 'My Way or the MTA' (n 4) 199.