19-403 Intellectual Property Classification & Protection
19-111 Criteria for Scientific Publication

EXECUTIVE SUMMARY

Cancer research is at the core of MD Anderson's mission. The Institution spends more than $850M annually to support research efforts. It is critical that we protect the intellectual property that results from that research.

Internal Audit assessed the controls in place to protect intellectual property. As part of this assessment, we also reviewed the publication process to determine how the current processes protect the Institution and principal investigators against allegations of scientific misconduct.

Publishing Process

Scientific publications and the data supporting those publications are the responsibility of the investigator. MD Anderson faculty published over 13,100 articles from January 2018 through August 2019.

Publications include research articles, technical reports, short communications, letters to the editor, review articles or other scholarly contributions to scientific literature in print or electronic format.

Publishing processes vary among investigators and departments. Several departments (i.e. Research Library, Scientific Publication, etc.) provide support to investigators during the publication process. This includes searching for literature, writing and editing manuscripts, author acknowledgement, data analysis, managing data, and plagiarism reviews. However, investigators do not use these services consistently or follow standard publishing processes.

Investigators are facing a rising number of allegations and cases of research misconduct. Investigators and the Institution must take steps to protect and defend their research from such allegations.

Intellectual Property Process

Most organizations view intellectual property as their single most important asset. In today's market, intellectual property makes up 80% of the value of S&P 500 companies, according to the Harvard Business Review. Intellectual property (IP) is defined by MD Anderson (MDA) as any invention, discovery, creation, know-how, trade secret, technology, scientific or technological development, research data, works of authorship, computer software, or other intellectual property that is owned by the Board, regardless of whether it is subject to protection under patent, trademark, copyright, or other laws.

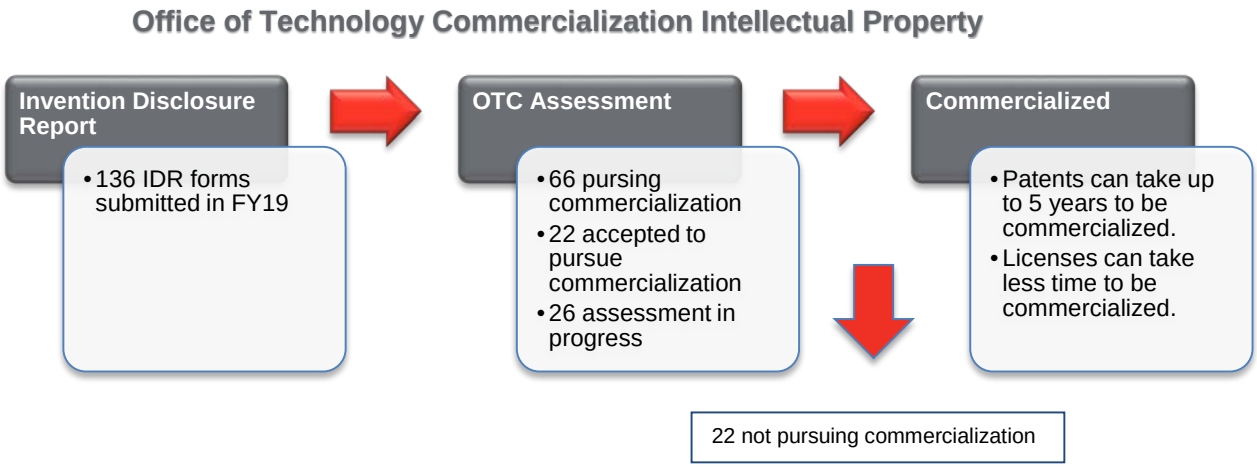
As MD Anderson investigators discover and publish critical research, it is important to protect its intellectual property. The proliferation of research data and numerous collaborations require clear guidance and expectations for safeguarding the institution's assets and data.

Patents and Licenses Ranges (FY15 – FY 18)

- 1246 Active Patents and as of 8/31/18
- 1254 Pending Patent Applications as of 8/31/18
- 232 Active License Agreements as of 8/31/18
- Approx. 239 – 358 Patent Applications Filed annually
- Approx. 198 – 232 Active License Agreements annually
- Approx. $12M – $178M License Income annually

The Center for Entrepreneurship Advancement (CEA), Strategic Industry Ventures (SIV), and the Office of Technology Commercialization (OTC) support the processes for identifying and commercializing intellectual property.

Intellectual property is disclosed through the Invention Disclosure Report (IDR). The Office of Technology Commercialization (OTC) assesses the IDR to determine whether to patent or license the intellectual property. See below for the status of IDRs initiated in FY 2019:



Audit Results:

Overall, Internal Audit noted a need for increased awareness of processes for protecting intellectual property and the integrity of publications. Internal Audit identified the following opportunities for improvement to better protect the Institution and investigators when publishing or managing intellectual property:

Publishing Process

- Consider developing consistent guidelines and review processes for scientific publications.
- Implement advanced data integrity tools to improve the process for responding to research misconduct allegations.
- Improve data management through consistent naming conventions and organization.

Intellectual Property Process

- Increase awareness to ensure intellectual property is protected.
- Enhance access controls for the Invention Disclosure Application (Inteum).

Additionally, management should continue to advance the data classification initiative to enable the data tagging and safeguarding of data as noted in the '2017- 401 Protection of Research Data' audit.

There have been several Data Governance and Data Management initiatives over the last few years. Management should continue to drive these initiatives to create a strong platform from which to govern data sources and research data.

Data Initiatives
• Electronic Notebook (ELN) • Data Endurance Committee • Oncology Data Foundation • Working Research Data Workgroup • Electronic and Data Capturing Project • Data Classification Initiative

Management Summary Response:

Management agrees with the observations and recommendations and has developed action plans to be implemented on or before the dates noted on the response to each observation in the report.

Appendix A outlines the objective, scope, and methodology for this project.

Number of Priority Findings to be monitored by UT System: *None*
A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"

The courtesy and cooperation extended by the personnel in the Information Technology department are sincerely appreciated.

Sherri Magnus

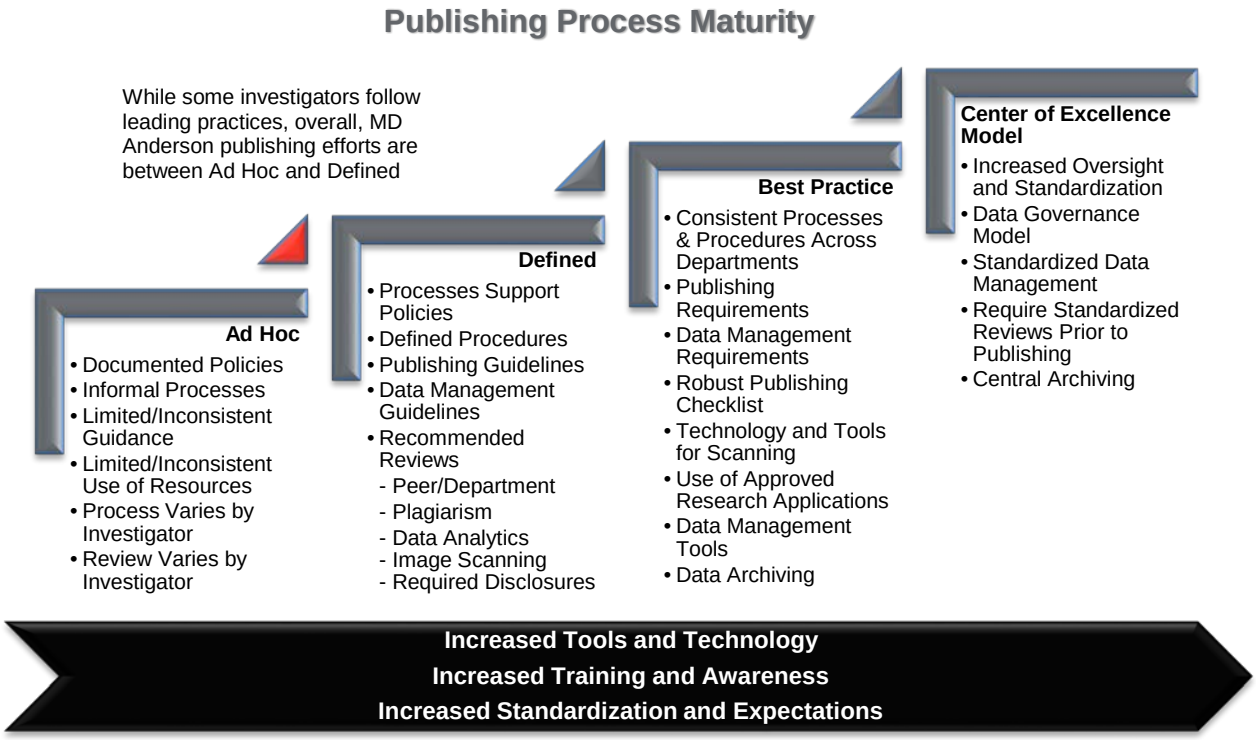
Sherri Magnus, CPA, CIA, CFE, CRMA
Vice President & Chief Audit Officer
August 30, 2019

Observation 1:

Consider Establishing Uniform Review Process Prior to Publication ***RANKING: High***

The Institution does not currently have a uniform review process prior to publishing scientific articles. The publication process varies among investigators and departments. There are inconsistent publishing guidelines and levels of awareness of publishing requirements. Some departments do not require any formal reviews or analysis prior to publishing, while others require peer reviews, plagiarism scans, data analytics, and image reviews to be performed before publishing. For example, Therapeutics Discovery developed a checklist that includes reviews to validate the data and images prior to publication. Well known research organizations have implemented similar research checklists as a best practice to guide the publication processes.

Inconsistent publication practices increases the risk of submitting research publications without thorough review and analysis of the publication and supporting data. Without a review of images, there could be accidental inclusion of images which may trigger questions related to research integrity. Additionally, articles could be published without adequate disclosures of funding or conflicts of interest.



Recommendation
MD Anderson should develop guidelines and expectations for publishing. Management should develop on-demand training at a detailed level sufficient to provide specific working practice expectations and best practices. A 'publishing checklist' or 'top ten things to remember' are helpful tools to encourage better publishing practices.

As management moves along the maturity model above, consider additional tools and processes which could be provided to protect investigators against potential allegations. Additionally management should consider whether these could be provided centrally through a Publishing Center of Excellence.

Management's Action Plan:
Executive Leadership Team Member: Dr. Giulio Draetta
Owner: Tania Secrest
Implementation Date: August 31, 2020

Management will assess current publishing processes and identify best practices. By 8/31/2020, management will implement data integrity training to provide guidelines and expectations for publishing.

Observation 2:
Enhance Data Integrity Tools ***RANKING: High***

Data integrity tools on the market can scan data and images to identify anomalies or alteration of data or images. Individuals and third parties are using these tools to scan research publications, and then use the results as rationale to file allegations of research misconduct against investigators. The Office of Inspector General, U.S. Department of the Interior (DOI OIG) uses these tools to investigate allegations of research misconduct. MD Anderson does not currently utilize such tools to analyze data or images prior to publishing

The number of research misconduct allegations and cases is increasing. MD Anderson is at a disadvantage in performing their own investigation of alleged research misconduct violations. It is difficult to defend against the allegations without these data integrity tools.

During an investigation, the investigator's IT assets and research data are seized, preventing ongoing research from progressing. If not defended in a timely manner, the reputation of the investigator and MD Anderson are at risk.

Recommendation
MD Anderson should consider obtaining and implementing advanced tools to perform analysis of data and images to enable the Institution to properly investigate and defend investigators against research misconduct allegations.

Management's Action Plan:
Executive Leadership Team Member: Dr. Giulio Draetta
Owner: Tania Secrest
Implementation Date: August 31, 2020

Management will evaluate data integrity tools available and implement a communication plan after a thorough evaluation.

Observation 3:
Improve Data Management to Ensure Data Integrity ***RANKING: High***

Cancer research generates hard data (glass slides, films, tumor blocks, etc.) and electronic data (medical records, bioinformatics data, genetic data, etc.). Policies require that data is retained, but they don't define how to prevent alterations to data or how to organize data in a manner to be easily located when needed. Investigators receive inconsistent training and education on how to organize their data and maintain data integrity.

With multiple researchers working on a project, multiple versions of data are created and may be stored in different locations. Investigators do not consistently follow naming conventions or organize their data in a consistent manner. Final versions of test results supporting conclusions are not consistently secured in a known location or archived.

Investigators must be able to demonstrate the integrity of their data, including verification that it has not be altered. This is necessary to ensure prompt response to the increasing number of research misconduct allegations.

Recommendation
MD Anderson should develop research data management guidelines and best practices to safeguard supporting data. Electronic notebooks and other research tools may address some of these issues, but they should be utilized in a consistent manner. For example, management should consider flagging and archiving final results and data that support conclusions so they can be easily located and protected from alteration. While copies of the data could be used for additional ongoing research, archived data should be secured and no longer modifiable.

MD Anderson should provide training on data management to ensure all investigators understand the guidelines, expectations and best practices. As an example, data management training should address expectations and best practices including:

Hard Data (slides, notebooks, etc.)	Electronic Data
Physically secured (locked key)	Access appropriately restricted
Indexed and labeled	Data source understanding
Checked in and out when in use	Validation of data requests
Inventoried on a periodic basis	Organized using common file structure
Flag and Archive final conclusions/evidence	Common naming conventions and indexing
Backup scanned copies where appropriate	All versions stored in common location
	Flag and Archive final conclusions/evidence
	Backup servers/data regularly

Management's Action Plan:
Executive Leadership Team Member: Dr. Giulio Draetta
Owner: Tania Secrest
Implementation Date: August 31, 2020

Management will evaluate current data management policies, best practices and guidelines, and provide additional detail and guidance. Management will implement a communication plan by 3/31/2020 and data management training will be implemented by 8/31/2020.

Observation 4:
Increase Awareness of Intellectual Property Processes ***RANKING: Moderate***

Several departments support the intellectual property and commercialization process. The Office of Technology Commercialization (OTC) evaluates potential intellectual property as reported in Invention Disclosure Reports (IDR). OTC determines whether the Institution would like to move forward with patenting or licensing intellectual property and oversees the legal process to do so. Several investigators work closely with OTC, identifying potential intellectual property throughout various stages of their research. However, based on inquiries of several investigators, researchers may not consistently understand how or when to identify intellectual property or the processes to protect it.

Intellectual Property & Commercialization
Center for Entrepreneurship Advancement (CEA) Provides resources to guide the intellectual property and commercialization process
Strategic Industry Ventures (SIV) Oversees strategic collaborations with external partners
Office of Technology Commercialization (OTC) Protects ideas and inventions through patent and licensing

Some investigators may publish without considering whether they have potential intellectual property or contacting OTC. Once published it limits the ability to protect intellectual property rights and/or commercialize the intellectual property.

Recommendation
MD Anderson should develop an awareness and communication plan to improve understanding of the processes related to protecting intellectual property. Management should provide additional information on intellectual property processes through education and awareness programs. Management should consider developing a checklist or questionnaire to help trigger the investigator to question whether they have potential intellectual property that should be protected.

Management's Action Plan:
Executive Leadership Team Member: Ferran Prat
Owner: Christopher Taylor
Implementation Date: August 31, 2020

CEA will continue to build a strategic model that allows MD Anderson to raise awareness, build a community, educate investigators and provide a common clear starting point to engage in intellectual property management. We will develop tools and training to increase awareness of the intellectual property process and create more connectivity with resources and key stakeholders throughout the commercialization process from ideation to market.

Observation 5:
Enhance Inteum Access Controls ***RANKING: Moderate***

Inteum is an application used to manage the intellectual property process. It contains the Invention Disclosure Report (IDR) as well as patent, licensing, and royalty details. The Office of Technology Commercialization (OTC) follows a formal process for granting access to Inteum when new employees join the office, or when creators enter the Inteum Inventor Portal for the first time. Removal of access to Inteum is informal, and the OTC relies on Institutional security controls (e.g. removal of Active Directory account and disablement of DUO authentication).

A new web-based front end, Inteum Inventor Portal, will go live in Fall 2019. Inteum Inventor Portal will allow creators to draft, submit, and view their IDRs' status. During the drafting phase of an IDR, creators will be able to grant access to other creators. Once the IDR has been "submitted," creators will no longer be able to grant access. Inventor Portal will require users to have MD Anderson intranet access, Active Directory accounts, and DUO authentication. However, allowing creators to grant access to others increases the risk of inappropriate access to IDRs.

Recommendation
Management should develop formalized processes for managing access to Inteum to ensure only appropriate users have access. Management could address this through system configurations, reviewing or approving new user access, or periodically reviewing access.

Management's Action Plan:
Executive Leadership Team Member: Ferran Prat
Owner: Andrew Dennis
Implementation Date: February 28, 2020

1. *When OTC employees leave OTC, their user access to Inteum can be disabled or deleted immediately. On a quarterly basis, former employees can be queried against user access and such user access can be disabled or deleted.*
2. *The process for accepting IDRs will involve querying for 0% Creators, and such individuals will be removed from the IDR unless there is a justification for allowing such Creators to remain on the IDR. Thus only true Creators and OTC-permitted Creators will have access to their respective IDRs.*
3. *We will determine whether additional access controls and/or processes are needed once the system is operational in September.*

Appendix A

Objective, Scope and Methodology:
The objective of this engagement was to evaluate the current policies and procedures as it relates to the identification and protection of intellectual property, the publication process, and the supporting data integrity. Specifically our objectives included:

1. Evaluate the policies and procedures to protect intellectual property, including:
    a. Data classification
    b. Precautions to protect confidential and proprietary data
    c. Accessibility to and monitoring of data accessible to students and visiting scientists
2. Evaluate the controls and processes in place to ensure the integrity of content for scientific/research publication
3. Determine whether controls and processes are in alignment with industry standards and best practice.
4. Provide recommendations to enhance the controls and improve the efficiency and effectiveness of the processes.

Our procedures conducted during the months of July - August 2019 included the following activities:

- Interviewed key personnel across the Institution to obtain an understanding of the processes and policies for identifying and protecting intellectual property as well as the publication process.
- Evaluated the processes for publishing and protecting the supporting data by inquiring with departments and principal investigators. Although aspects of our inquiries discussed disclosures of funding and conflicts of interest to be included in guidance, we did not assess the effectiveness of these disclosures in publications.
- Evaluated the effectiveness of controls and processes in place for monitoring and protecting intellectual property by inquiring with departments and principal investigators and selecting samples for testing.
- Evaluated the applications and data repositories used to compile and store the associated research data for adequate security controls and compliance with Institutional policy.
- Analyzed supporting policies, procedures, and supporting documentation
- Analyzed monitoring and reporting related to intellectual property and publications

Our internal audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing* and *Government Auditing Standards*.

Number of Priority Findings to be monitored by UT System: *None*
A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"