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Bayh-Dole Reporting
and Highlights of iEdison Software Upgrades

Welcoming remarks will begin at
11:55 a.m. Eastern Time.

The formal presentation will begin at Noon Eastern

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Bayh-Dole Reporting
and Highlights of iEdison Software Upgrades

Moderator:
Nicole Honoree, MSPP, RTTP, LSU Health Sciences
Center – New Orleans
Speakers:
Scott Cooper, J.D., National Institutes of Health (NIH)
Mary Frances Deutsch, National Institutes of Health (NIH)
Michele O'Shea, Borman and Company LLC

July 7, 2015

Thank you to our sponsors.

Questions?

We will be taking questions at the conclusion of the presentation.

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Operator Assistance

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Other issues: +1-847-559-0846

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• **Access to AUTM Publications**
– *AUTM Better World Report*
– AUTM Salary Survey
– AUTM Technology Transfer Practice Manual
– AUTM Licensing Activity Survey (currently for United States and Canada)
– AUTM Update

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– Meeting proceedings and presentations
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– Access to post data on the **Global Technology Portal**

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Nicole Honoree,
LSU Health Sciences Center – New Orleans

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Scott Cooper,
National Institutes of Health (NIH)

Mary Frances Deutsch,
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Borman and Company LLC

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The following presentation reflects the personal views and thoughts of Scott Cooper, Mary Fran Deutsch, Michele O'Shea and Nicole Honoree and is not to be construed as representing in any way the corporate views or advice of the NIH, Borman and Company LLC, or LSU Health - New Orleans and their Affiliates, Subsidiaries or Divisions, nor the views or advice of the Association of University Technology Managers (AUTM). The content is solely for purposes of discussion and illustration, and is not to be considered legal advice.

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Bayh-Dole Reporting and Highlights of iEdison Software Upgrades

Scott Cooper
Grants Policy Analyst
and
Mary Fran Deutsch
Grants Policy Analyst

Division of Extramural Inventions & Technology Resources (DEITR)
Office of Policy for Extramural Research Administration (OPERA)
Office of Extramural Research (OER)

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Discussion Points

- Introduction
- Highlights of recent iEdison Updates and Releases
- Top 10 Most Common Grantee Questions
- Expanded Resources on iEdison and Reporting requirements
- Contact Information

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Introduction

- Good News:
  - ❖ No new Bayh-Dole reporting requirements since 1980 in 2015 - **35 YEARS**.

- With that Good News comes an overall increase in reporting due to the increase in the cumulative number of NIH funded inventions over these 35 years.

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- **iEdison is turning 20 years old!** The "Edison" system was initially deployed by the NIH in October 1995.
  - "Edison" was the first electronic system in the government to support government administrative requirements.
  - "Edison" began with four institutions pilot testing the system in the Spring of 1995.
- In 1997, with the addition of the National Science Foundation (NSF) and the U.S. Agency for International Development (USAID) came the introduction of Interagency Edison (**iEdison)**.
- By 2003, (iEdison II) approximately 500 grantee/contractor organizations were using the system and 18 federal agencies were participating.

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- **Today –** iEdison is used by 32 Federal agencies or offices and their grantees/contractors for Bayh-Dole reporting.
- Over the past couple of years, there have been many improvements and fixes to iEdison.
- NIH has participated in more webinars and electronically in more AUTM meetings.
- October AUTM Tools Course: NIH will participate in person!

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Highlights of iEdison Updates and Releases
2014

- iEdison helpdesk support integrated with the eRA Enterprise System Helpdesk. Advantage: more people are able to assist with iEdison & answer questions.
- Technical infrastructure improvements including closer integration with eRA Enterprise System. Advantage: NIH will use a similar system that NIH awardees use.
- Unicode migration, system now recognize special characters e.g. β (Greek Beta).
- Document Upload functionality was enhanced.
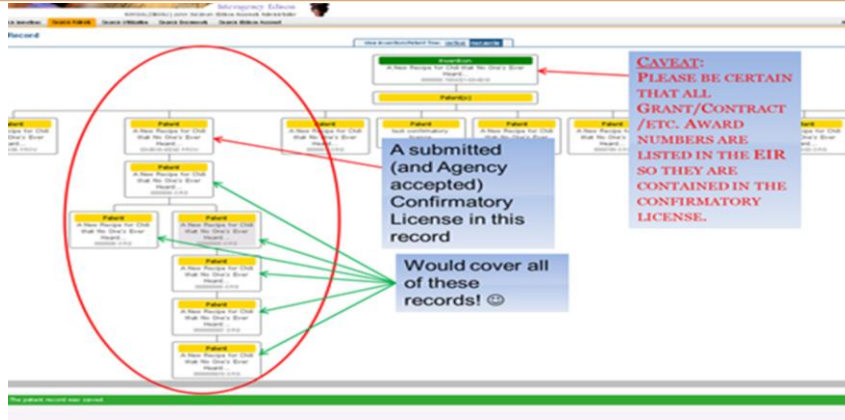- NIH ability to deactivate and reactivate notification messages.

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Highlights of iEdison Updates and Releases
2014

- Notification message page improved to allow more search results to appear.
- Added an anchor point to the search results so a user no longer must scroll down again when clicking to the next page.
- Fixes to the Upload iEdison Invention Report Data Stream.
- New and Improved User Interface for Patent Page, Patent Search, and Patent Linking Hierarchy.
- Patent linking allows a patent to have multiple children with linked confirmatory licenses & disclosures.
- Users can now add a date range for a report of a Grantee's Invention Reports. See the Generate Invention Report link. The Invention Report generated will also exclude transferred and voided inventions.
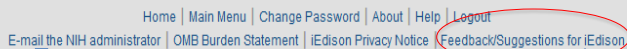
**Screen Shot showing new
Patent Overview and Linking**

Highlights of iEdison Updates and Releases 2015

January

- Ability to Send Feedback/Suggestions for iEdison. iEdison now has the ability to access the eRA Help Desk Footprints system directly via a **Feedback/Suggestions for iEdison** hyperlink located at the bottom of every screen.

- When the Feedback/Suggestions for iEdison hyperlink is clicked, the system displays the iEdison Commons Support Portal screen. The system automatically completes the Last Name, First Name, Email, Customer ID, and Organization information. Required fields are in red text and noted by an asterisk.

Highlights of iEdison Updates and Releases 2015

January (Cont'd)

- Patent Records that have been waived **can't** be modified by: Extramural TTO Admin, Extramural TTO User, or Inventors
- Changes to how the Confirmatory License (CL) is generated. The CL Form's Patent or Application Serial No. and the U.S. Filing/Issue Date fields are now generated based on the earliest U.S. patent information provided in the Patent Report.
- iEdison will look at Provisional, Non-Provisional, Patent Issued, and Patent Cooperation Treaty (PCT) numbers and filing dates, if provided, and populate the CL Form's Patent or Application Serial No. and the U.S. Filing/Issue Date fields accordingly.

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Highlights of iEdison Updates and Releases
2015

March

- Waiver requests **MUST** be submitted via iEdison.

  See NIH Guide Notice NOT-OD-15-080, Notice Regarding Requirement of Grantees and Contractors to Submit Invention Disclosures, Related Reports and Documents Via iEdison: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-080.html#sthash.ogR7nzk7.dpuf

- Patent Notification Messages simplified based on whether the Government Support Clause has been submitted or rejected rather than on the type of patent. Only affects messages generated after the deployment date.

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Highlights of iEdison Updates and Releases
2015
Important changes affecting when Inventions can be waived.

March

On the Modify Invention Report screen, certain NIH Inventions **may no**t be set to *Not Elect Title* in the Invention Status box if the invention has:

❑ **outstanding notifications** regarding a **missing, submitted, or rejected Confirmatory License, Government Support Clause, Invention Disclosure Documents,** or

❑messages that **Utilization reports are due**, including for the current Fiscal year, or if the **Fiscal Month** that begins the organization's reporting year is missing.

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Highlights of iEdison Updates and Releases
2015

March (Cont'd)

- Changes affecting when Inventions can be Waived --

    If these rules are not followed, the following error messages will display:

    - "A Utilization Report must be submitted for the Fiscal Year <Fiscal Year> before the invention may be set to Not Elect Title status. The following notification messages must be cleared by the Agency before you may Not Elect Title to this invention <Message Number> "

    - "The following notifications must be cleared before you may Not Elect Title to this invention: <Message Number> Also, any messages suppressed by the institution also require resolution"

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Highlights of iEdison Updates and Releases
2015

April

- Removed the "paper option" for files uploaded on Invention and Patent Reports.

- Message 260 (5260) Provisional Patent Application Due to Expire
    - Triggers clarified.
        - Invention Report's status is **not: Record Voided, Transferred or Not Elect Title, AND**
        - The Patent Report's status **is Institution Retains Rights AND**
        - There is a Provisional Patent Application Date in the Patent Record **AND**
        - There isn't a PCT Filing Date, Non-Provisional Application Date, and Patent Issue Date, **AND**
        - The Patent Record is not a Parent Patent, **AND**
        - The difference between the Provisional Patent Application Date and the present date is > ten months.

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Highlights of iEdison Updates and Releases
2015

- April (Cont'd)
  - Miscellaneous Fixes
    - Suppressed Messages are now Automatically Unsuppressed after 30 Days
    - DOE Email Notification for new Inventions/Patents now Includes DOE Award Number. The DOE "S" Number now Appears when Exporting Invention and Patent Reports

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Highlights of iEdison Updates and Releases
2015

June

- Users may not Waive a Patent Report with Outstanding Notifications *for NIH Inventions*
  - When an external user requests to waive a patent on NIH Extramural Inventions Report (EIR), the system will check for the following:
    - Missing Government Support Clause (GSC)
    - Missing Confirmatory License (CL)
    - CL is rejected
    - GSC is rejected

Highlights of iEdison Updates and Releases

- June (Cont'd)
  - If any of the aforementioned conditions exist, the following error message(s) display accordingly when the **Submit** button is clicked:
    - *The following notifications must be cleared before this Patent may be Waived: <EXTRAMURAL NOTIFICATION NUMBER>. Also, any messages suppressed by the institution also require resolution.*
    - Example missing a GSC - *"This patent record may not be waived until the Government Support clause is added to the Patent and attached to the patent record and accepted by the Government."*

Highlights of iEdison Updates and Releases

June (Cont'd)

- Associated Patent Reports must be waived before waiving an Invention Report
  - If not, the following message will be displayed:
    - "*Before you may Not-Elect-Title to this Invention, all associated Patents must be Waived.*"
- iEdison will also verify that an Invention Disclosure has been accepted.
  - If not, the following message will be displayed:
    - "*This invention record cannot be waived until the disclosure document is accepted by the Government.*"

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Highlights of iEdison Updates and Releases

June (Cont'd)

- Report requirement rules included in the March 2015 release are also enforced for an NIH Invention through the *Data Stream Upload.*
- Utilization Report Reminders are available for certain DOT contracts.

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What's Next for iEdison

- Additional updating of messages to eliminate inaccurate or duplicate messages.

- NIH has been working with other Federal Agencies and Workgroup/User Group to help identify and prioritize iEdison issues.

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Frequently Asked Questions (FAQs)

- From the iEdison home page, click on "Frequently Asked Questions."
- **90** FAQs posted including definitions of important terms, more to come!
- New questions are marked with a yellow box with the word NEW (60 days).
- iEdison - Frequently Asked Questions (FAQs)
  - http://grants.nih.gov/grants/frequent_questions.htm

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Top 10 Most Frequently Asked Questions
(in no particular order)

10 –This is all so new to me. Do you have any webinars or instructional-type videos posted on the Internet that will guide me through the invention reporting process?

A. Thanks for asking Mr. Strawman McEdisonuser! As a matter of fact we do! The NIH has an NIH Grants channel on YouTube! Here you'll find videos on topics ranging from the NIH Grants Process, Peer Review, eRA, and of course Extramural Inventions & Technology Resources (which also covers contracts). We have webinars that will help you better understand Confirmatory Licenses, Government Support Clauses, and Invention Disclosures. And stay tuned. There's more to come.

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**Top 10 Most Frequently Asked Questions
(in no particular order)**

9 – If I upload a patent application, can that patent application satisfy the Invention Disclosure Report requirement?

A. You betcha! So long as the EIR Number or Invention Docket Number is included in the submission, the patent record containing the patent/patent application number has been reported in iEdison, and you upload proof that the patent application was filed with the USPTO, e.g., a USPTO submission receipt.

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**Top 10 Most Frequently Asked Questions
(in no particular order)**

8 – Uh-oh! I just found my Invention Disclosure under my couch cushion (along with a missing sock and a sardine sandwich). I know I should have reported my invention within the required 2 month period and it's been a year. Should I report it or will you not notice?

A. Always report the invention, even if it is late. Even if it's very late. Keep the sock and the sandwich.

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Top 10 Most Frequently Asked Questions
(in no particular order)

7 – Whoa Nellie! I just found out that Provisional, Non-Provisional, and PCT patent applications should all reside under the same Patent Report Form. I've been filling out a new form each time. Can I somehow link these report forms and eliminate some of these pesky notification messages?

A. You're in luck! You can establish Parent/Child linkages between related Patent Records.   Enter the Patent Docket Number of the preceding Patent Record into the "Parent Patent Docket Number" field of the Child Patent Record. Once that is done, Voila!, the Child is linked under the Parent record. Oh, and don't call me Nellie.

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Top 10 Most Frequently Asked Questions
(in no particular order)

6 – What is a Government Support Clause and what are its requirements?

A. The Government Support Clause (GSC), whether contained in a provisional patent application, non-provisional patent application, or a Patent Corporation Treaty (PCT) (not necessary to include) patent application, must match **exactly** the following statement with the appropriate contract/grant numbers and Federal agency(s) identified):

"**This invention was made with government support under (identify the contract) awarded by (identify the Federal Agency). The government has certain rights in the invention.**" 37 CFR 401.14(f)(4)

To satisfy the Government Support Clause requirements, the Government Support Clause must be uploaded within the full Patent application along with the USPTO Filing receipt.

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Top 10 Most Frequently Asked Questions
(in no particular order)

5 – Sometimes. . . occasionally. . . infrequently . . . OK. You broke me. (You're good). A few times a month, I learn of additional or previously unknown funding sources AFTER a patent has issued (in some cases – a long time after issuance). Is it necessary to file a correction to the issued patent to add the additional funding information or can we just keep this between us and that plastic plant over there in the corner?

A. If a new funding source/award is discovered to have funded a patent after the patent has issued from a subject invention, you must add the award number to the EIR document and to iEdison, then obtain a certificate of correction from the PTO (upload that too) for the issued patent and a new confirmatory license (yes, upload that too) with all of the pertinent award numbers for recordation at the PTO.

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Top 10 Most Frequently Asked Questions
(in no particular order)

4 – Ruh-Ro!! I accidentally waived the rights to an invention. What do I do now?!

A. First, take a deep breath. Have a Scooby Snack. Then, please submit a written request to edison@od.nih.gov to have the subject invention status changed. The request must include in the subject invention status the reason(s) for the change. Please promptly inform us when you realize you accidentally waived the rights to an invention.

Top 10 Most Frequently Asked Questions
(in no particular order)

3 – OK. This is a stupid question. Especially after the first seven questions. But, what is an Extramural Invention Report (EIR) Number?

A. Hey now! There are no stupid questions. (Actually, there are. For example, what fruit do I use to make applesauce? But yours isn't a stupid question.) This number is automatically generated by the iEdison system for a new Invention Report after data has been submitted, checked for errors, and verified. It is unique for each reported invention and cannot be duplicated, modified, or reused.

Top 10 Most Frequently Asked Questions
(in no particular order)

2 – I sometimes forget where my keys are in the morning. So, it's no surprise that I forget my iEdison password from time to time. If I have forgotten my password, or have been locked out due to failed log-in attempts, what should I do?

A. You're not alone. (Hint: they're in the front pocket of your pants that you wore yesterday.) Users who have forgotten their passwords can request to reset their passwords. Select the *Forgot Password/Unlock Account?* link on the iEdison home page, and enter your User ID and email address in the required fields. Submitting this request generates a new, temporary password, which is sent to the email address listed in your user profile (Personal Profile). This temporary password will allow you to log in to iEdison, where you can create a new password of your choosing. See the iEdison Online Help for more information about logging into the system.

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Top 10 Most Frequently Asked Questions
(in no particular order)

1 – Try as I may, I cannot include the Non-Provisional Patent Application Data in the Provisional Patent record. What do I do?

A. Ahhh, you're ending with an easy one. Change the "Type of Patent Application" from PROV (Provisional) to ORD/UTIL (Non-provisional). That should do it.

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Expanded Resources on iEdison and Reporting

- iEdison Webinars
  - The NIH has an NIH Grants channel on YouTube! Here you'll find videos on topics ranging from the NIH Grants Process, Peer Review, eRA, and of course Extramural Inventions & Technology Resources (which also covers contracts). We have added webinars on:
    - Confirmatory Licenses,
    - Government Support Clauses, and
    - Invention Disclosures.
- And stay tuned. There's more to come!
    https://www.youtube.com/user/nihgrants

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Online Help, User Guides & Release Notes

- Online Help is available for:
  - Technology Transfer Office (TTO) Administrator, TTO User , Inventor
    See: http://era.nih.gov/erahelp/iEdison_Admin/default.htm
- User Guides
  - S2S User Guide (system to system) (PDF - 747 KB) - 6/24/2015
    http://inside.era.nih.gov/files/S2S_Web_Services_Guide_final_06-10-2015_revision.pdf
  - Technology Transfer Office (TTO) Administrator (PDF - 9.8 MB) - 06/1/2015
    http://era.nih.gov/iedison/iEdison_Administrator_userguide.pdf
  - TTO User (PDF - 9.5 MB) - 06/1/2015
    http://era.nih.gov/iedison/iEdison_User_userguide.pdf
  - Inventor - (PDF - 9 MB) - 06/1/2015
    http://era.nih.gov/iedison/iEdison_Inventor_userguide.pdf

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Where to Go if You Have Questions

- Division of Extramural Inventions and Technology Resources
  (DEITR) and iEdison contact the:
  - eRA iEdison Help Desk: edison@od.nih.gov
  - Toll-free: 1-866-504-9552
  - Phone: 301-435-1986
  - Hours: Mon-Fri, 7:30 a.m. to 5 p.m. Eastern Time (closed on federal holidays)

Invention Reporting Using Edison: Tips and Tricks from a User's Perspective

Michele O'Shea
Borman and Company

AUTM Webinar
July 7, 2015

Electronic Invention Reporting Using Edison

- All Institutions should be reporting via Edison

- Database consists of three main sections: Invention Disclosure Date, Patent Data, and Utilization Data

- Edison reporting requires less paperwork; notifications and documents are uploaded into the Edison system

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Electronic Invention Reporting Using Edison

- There may be a need to maintain data in two systems- TTO database as well as Edison database

- Federal Agencies that are not using Edison still require standard notifications via email/fax

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Electronic Invention Reporting Using Edison

- For Agencies not using Edison, need to check in grant/contract files to get contact information for invention reporting

- For jointly owned/jointly funded inventions, need to communicate with joint owner(s) re: Edison reporting

Electronic Invention Reporting Using Edison

- In some instances, awardees cannot sign confirmatory licenses and final invention statements on behalf of other institutions
- It can be challenging to coordinate reporting between institutions
- Need to ensure that your institution or another institution has taken responsibility for invention reporting on jointly owned/funded inventions (e.g., IIA)

Electronic Invention Reporting Using Edison

- You may receive reminders for information that you previously submitted to Edison; when this occurs, you may wish to notify the Primary Funding Agency
- Whenever possible, it is best to report inventions through Edison; additional agencies may use Edison in the future

Edison: Management of Reminders

- Can reminders be managed? (YES!)
- Will they ever completely go away? (NO)
- Suppression only enables you to remain in denial (Tempting but not recommended)
- Suppress Feature is for Individual User's View only (not Institution-Wide)
- Reminders can be reviewed by sponsor and by category (inventions, patents, utilization)

Types of Reminders

- **Disclosure not uploaded to Edison**: You may have previously mailed it. In this case you can upload it if it is available (in archives, etc.); otherwise you can send NIH a list of disclosures that fall into this category so they can check their records.

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Types of Reminders

- **Disclosure rejected due to insufficient description:** If after internal review your institution feels that the description is adequate you can ask NIH to review it and reconsider it for acceptance; you can also re-upload it with additional documents (manuscript, etc.)
- Going forward, you should review all disclosures prior to submission and ask inventor(s) to provide additional information up front to decrease these notifications

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Types of Reminders

- **Disclosure rejected because inventors/grant numbers/title do not match what is in the EIR:** The disclosure is only accurate as of the moment it is submitted; often additional inventors, grants, and title changes are received after the fact. Prior to acceptance by NIH, the disclosure information should be updated and resubmitted to avoid receiving a rejection notice.
- Once the disclosure is accepted by the system, it doesn't ask for additional disclosure information or an amended disclosure

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Types of Reminders

- **A confirmatory License is due**: Check the patent records first, as a license may in fact not be due. It is possible that the filings are not linked. A license is not due for each application, but if the filings are not linked Edison is programmed to ask for a license for each filing. You won't accurately be able to determine how many licenses are in fact due until the filings are linked in the system.

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Types of Reminders

- **Government Support Clause (GSC) does not have correct language**: Going forward you should request that the law firm add the exact statement. Going back, you may want to check with your TTO management to see if they will spend the time and money to go back and amend the filings/statements in which the statement is present but the wording is not exact (analysis of risk)

- If your institution chooses not to amend the GSC, it is recommended that you add an explanatory note to the record; the previous language "**may have rights**" is not approved (see next slide)

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Federal Support Clause

- "This invention was made with government support under (contract/grant) awarded by (Federal Agency). The government **has** certain rights in this invention."(37 CFR 401.14f(4))
- Need to include all applicable federal grants and contracts in Statement of Government Rights

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Tips on Linking Filings

- Edison will now allow you to link a filing to two or more filings in the patent table.
- When you enter a PCT application in the record for the utility, there is no way to let Edison know that the PCT is abandoned, because there is only one status field, and the utility application may be pending/issued. Another option is to enter the PCT separately and link it to the provisional or utility filing.

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Interim and Final Invention Reports

- Due to Federal Agency within 90 days of annual period as requested
- Grants and Contracts Office needs invention information from TTO in order to submit invention statement to Federal Agency
- NIH Grant offices check to confirm that invention information on final invention reports matches what is in Edison

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Summary

- Compliance is an ongoing task- you need to know what resources you have and prioritize accordingly
- Focus on having internal TTO procedures and using best efforts to comply
- Communicate with: PI's, Sponsored Programs
- Communicate with NIH and other Agencies and let them know about problems with reporting
- Maintain a Sense of Humor!

Contact:

Michele O'Shea
Consultant
Borman and Company
moshea@bormanandco.com

Questions? Comments?

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Discussion
and Q&A

Click the raise hand button.

When called on, press * 7 on your telephone keypad to un-mute your phone.

Press * 6 to re-mute your phone.

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Webinar Recordings

Basics of Technology Transfer for Licensing Professionals
Basic Patenting 101
Copyright Law and Content/Software Licensing
Equity Based License Agreements
Financial Conflicts of Interest
Marketing: Whether By Traditional or Social Media, the Value
Need to Know Basics of Technology Transfer for Support Staff
Negotiation of License Agreements
Nuts and Bolts for Compliance Under Federal Funding Awards
The Basics of Open Source Licensing
Tips for Managing MTAs
Triage
Valuation of Inventions and Patents
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