Cincinnati Children's Innovation Ventures (CCIV) / Inventor Service Level Expectations (SLE)



Outline of this Document

- Why work with CCIV
- What is CCIV
- How to work with CCIV
 - Research Tools
 - Commercialization
 - Sponsored Research



Why Work with CCIV



Why Work with CCIV

- Innovate Together with Cincinnati Children's Innovation Ventures
- Research or institutional experiences often lead to new ideas or discoveries that can benefit the public
- Typically, publication alone is not enough to ensure that the market will adopt an innovation
- We partner with companies or organizations that can make new products available to the market.
- Ensure we have the rights to transfer research materials
- Protect your interests when sending research materials or receiving funding (e.g., acknowledgement, publication, appropriate use, maintaining control of important background intellectual property)



Why Work with CCIV

- Bringing a product to market likely requires further research or clinical trials and is expensive
- Industry generally prefers to invest in a technology that has intellectual property protection – exclusivity creates the incentive to invest in the process when the relative cost of copying the product is low
- If you want to share in any **future revenue** generated from licensing your innovation



What is CCIV



Functional Groups

Portfolio Management

- Initial Review of all new technologies
- Responsible for managing the bulk of the portfolio
- Maintains primary Inventor(s) relationship
- Negotiates and Executes agreements related to portfolio technologies
- Submits technologies for Acceleration

Acceleration Management

- Each Manager is responsible for 1-5 projects, each encompassing 1 or more technologies.
- Provides in depth strategy for technology development
- Works closely with Inventor(s) to decide on strategy and collaborate on the needs for the technology
- Negotiates and Executes agreements related to Acceleration technologies

Patent Management

- Requests input from Innovation Ventures colleagues and Inventors to consider patent strategy
- Provides input to Innovation Ventures and Inventors around patent strategy
- Manages relationships with outside patent counsel

Program Management

- Develops ongoing relationships with long-term partners that fund development of CCHMC technologies
- Manages internal and external funding programs to help develop CCHMC technologies

Marketing

- Assists with market and competitive research
- Identifies marketing leads at companies we do not have existing relationships with
- Standardizes external and internal communications from Innovation Ventures
- Designs educational opportunities related to innovation within CCHMC

Finance & Data Management

- Receives and distributes revenue received by our licensees
- Manages payment to patent counsel and other vendors
- Manages our internal database
- Reports inventions to government funders



CCIV Programs and Development Opportunities

Innovation Fund

An internal development fund with RFPs 2x/year

BridgeBio Research Alliance

Multi-year collaboration to advance transformational therapies

BioMarin Open Innovation Program

Focused on genetic-based diseases of at least 1:50,000

Pfizer Centers for Therapeutic Innovation (CTI)

Novel Targets in Inflammation & Immunology, Internal Medicine, Oncology, and Rare Diseases

Sanofi Innovation Awards (iAwards)

Therapeutics in immune-oncology, molecular oncology, immunology & inflammation, rare diseases, diabetes, and cardiovascular diseases

Takeda Research Collaboration

Multi-year collaboration to advance early-stage CNS, oncology, GI, and rare disease therapeutics

CCHMC Translational Core Labs

Vector design and manufacturing resources

Venture Partnerships

CincyTech, Orange Grove Bio, Fortress, Roivant, 5AM, and others

Ohio Third Frontier Technology Validation Start-up Fund (TVSF)

Ben-Gurion Cincinnati Children's Collaborative (KidStart in Israel)

Medical device and digital health co-innovation





















Our Portfolio Asset Classes



Small Molecule Therapies



Biologic, Cell & Gene Therapies



Diagnostics & Medical Devices

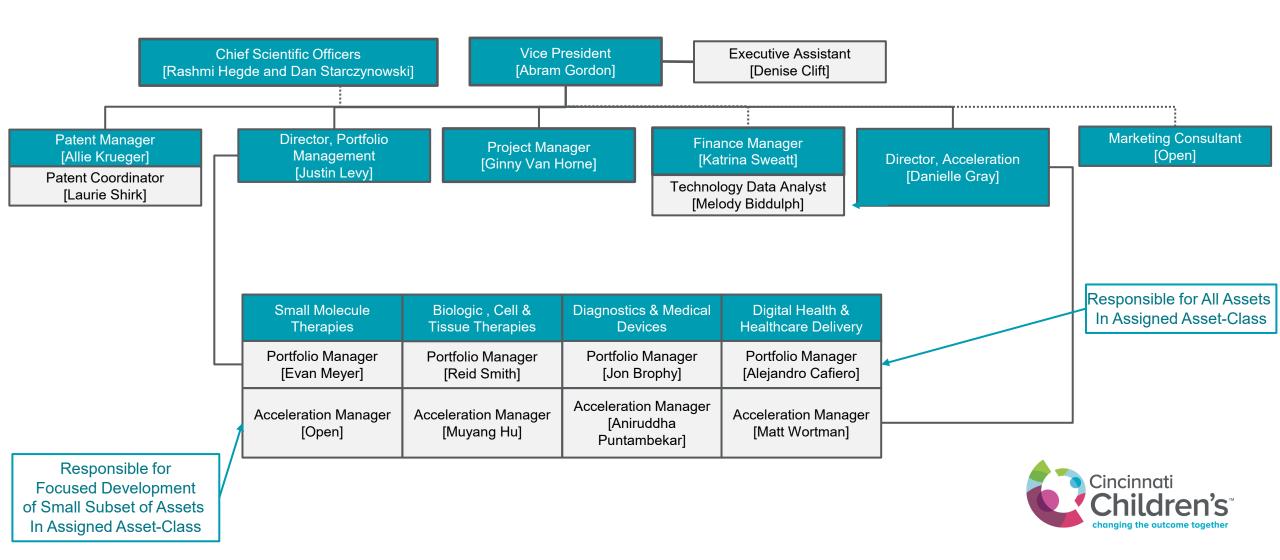


Digital Health & Care Delivery

Find CCIV on: CenterLink's Research tab (or keyword search "ventures")



Our Org Chart



How to Work with CCIV



When to disclose?

 Publication or presentation before a patent filing usually results in the inability to ultimately get a patent

 So, disclose to Innovation Ventures at least 30 days before you publish or present so we can discuss if IP makes sense in your case



Where to start?

AT LEAST 30 DAYS BEFORE submitting a manuscript or speaking at a conference, be sure to contact us

- Submit a disclosure via the Inventor Portal
 - See <u>Types of Disclosures</u>
- Contact information can be found on our <u>Centerlink Page</u>

Key information includes:

- The names of the Inventor(s)s, their respective institution, and their contributions
- Any funding received to support the invention and associated grant numbers
- A detailed description of the invention, along with a brief statement indicating what the invention is and what it can be used for
- A copy of any anticipated dissertation, poster, presentation, manuscript, etc, if available, and the date of planned publication or presentation
- Any 3rd party materials used in creating/developing the invention



Types of Disclosures

Invention Disclosures – ideas with some proof of concept

- <u>Therapeutic & Diagnostic Asset Classes:</u> may include in vitro or in vivo data justifying a novel target, validation of a novel target, pharmacologic evidence that modulating a novel target may treat an indication, a novel and proprietary therapeutic approach, or validated markers with AUC better than current standard of care
- <u>Medical Device, Digital Health and Care Delivery Asset Classes:</u> may include a potential designs or solutions that are devices, software or informational; a 3D printed model; a software wireframe; or a working device or software prototype

Research & Development Disclosures (RDs) – early-stage concepts

- <u>Therapeutic & Diagnostic Asset Classes:</u> early-stage data supporting a novel mechanism or marker that could lead to improvement of clinical care
- <u>Medical Device, Digital Health and Care Delivery Asset Classes:</u> identification of a patient need or clinical need at the concept stage or earlier

Research Tool Disclosures (RTs) – items for use by other researchers

- Biologic Research Tools: include proteins, cell lines, and animal models
- Copyright Research Tools: include research software, questionnaires, surveys, and manuals



How to Work with CCIV Process & Expectations



CCIV Processes

- 1. Commercialization Process of Invention Disclosures and R&D Disclosures
- 2. <u>Sending and Receipt of Biologic and Copyright Research</u>
 <u>Tools</u>
- 3. Sponsored Research



1. Commercialization Process of Invention Disclosures (with proof of concept) and R&D Disclosures (without proof of concept)



EVALUATION

Disclosure Submission & Acknowledgement

Acknowledgement
 ≤ 3 business days
 of disclosure
 submission; Urgent
 patent filing
 decision within ≤14
 days

Disclosure Reporting & Assessment

• ≤ 30 days of disclosure submission

Review Process & Disposition

• ≤120 days of meeting with Inventor(s)

MANAGEMENT

Initial Commercial Strategy

> • ≤ 30 days of Review Process & Disposition

Intellectual Property Management

> Timelines determined by patent offices

Marketing

 Ongoing once technology reaches "Marketing" status Agreement Due
Diligence, Negotiation,
& Execution

- Timeline determined by partner
- Innovation Ventures to follow up every 2 weeks

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Disclosure Submission and Acknowledgment



Disclosure Reporting and Assessment



Review Process and Disposition

Inventor(s)

≥ 30 days prior to a public release

- Submit a disclosure 30 days prior to a dissertation, publication, poster, abstract, public presentation, discussions outside of immediate collaborators, or other public release
- Fill out a complete disclosure, and respond to any requested missing information
- For federal reporting requirements, this, at a minimum, includes:
 - The names of the Inventor(s)s, their respective institution, and their contributions
 - Any funding received to support the invention and associated grant numbers
 - A detailed description of the invention, along with a brief statement indicating what the invention is and what it can be used for
 - A copy of any anticipated dissertation, poster, presentation, manuscript, etc, if available, and the date of planned publication or presentation
 - Any 3rd party materials used in creating/developing the invention

Innovation Ventures

≤ 3 business days of Disclosure Submission

- Assigned to a portfolio manager
- <u>Deliverables:</u>
 - Automated email from CCIV software acknowledging receipt

≤ 14 days of Disclosure Submission

- Confirm all necessary information is included in the disclosure
- Will review Inventors' publication timeline to understand if any urgent decisions need to be made
- <u>Deliverables:</u>
 - Email from portfolio manager to Inventor(s) acknowledging receipt
 - Communication if a patent will be filed prior to any imminent public disclosure

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Disclosure Reporting & Assessment



Review Process and Disposition

Inventor(s)

≤ 60 days of completed disclosure

- Iterative meetings to provide Innovation Ventures with sufficient understanding of the invention
- To the extent known, provide Innovation Ventures with relevant background publications, unpublished data related to the invention, grant submissions, details related to the potential customer or patient, and academic colleagues and/or industry working in the space
- Report inventions on grant close-out forms, as needed

Innovation Ventures

≤ 30 days of completed disclosure

- Report to sponsor, if any. Should match inventions on grant close-out forms completed by Inventor(s)
- Review and log any 3rd party obligations (e.g., funding agreements, material transfer agreements)
- Reach out to any institution that is a co-owner to the invention
- Deliverable:
 - Meeting with Inventor(s) to be scheduled



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Initial Commercial Strategy

• ≤ 30 days of Review Process & Disposition Intellectual Property Management

> Timelines determined by patent offices

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Disclosure Submission and Acknowledgment



Disclosure Reporting and Assessment



Review Process and Disposition

Inventor(s)

≤ 90 days of completed disclosure

- Allow Innovation Ventures to confidentially share invention information with internal and external reviewers
- Availability to answer questions from Innovation Ventures or reviewers
- Availability to discuss strategy of commercialization with Innovation Ventures

Innovation Ventures

≤ 120 days of meeting with Inventor(s)

- If a patent was filed, there may be further search of patent/publication literature
- <u>Deliverables</u>:
 - Determination by Innovation Ventures whether institution will pursue commercialization, or if <u>Inventor(s) Driven or Shared Responsibility</u>



Disposition Options Brief Description

Inventor(s) Driven Experimentation based on CCIV Feedback - ~ 40 projects per Portfolio Manager

- Technology enters Innovation Ventures portfolio, <u>but</u> requires additional development by Inventor(s)
- Intellectual property determined by Innovation Ventures in conjunction with Inventor(s)
- Development pathway provided based on template
- Limited marketing activity by Innovation Ventures until a specific milestone is hit

Shared Responsibility to Drive to Commercialization Exit - ~ 8 projects per Portfolio Manager

- Technology enters Innovation Ventures portfolio
- Intellectual property and marketing strategies determined by Innovation Ventures in conjunction with Inventor(s)
- Development pathway discussed based on template, and alignment developed between Innovation Ventures and Inventor(s)
- Technology is potentially eligible to enter Acceleration

Not Pursued for Commercialization

- Technology will not enter Innovation Ventures portfolio
- There will be discussion on what additional information or data, if any, will support moving into the portfolio
- Any agreement related to the invention (e.g., confidentiality agreements, service agreements, research
 collaboration agreements, sponsored research agreements) can be submitted via <u>Huron (HRS)</u> (if research related) or
 <u>Peoplesoft</u> (if not research related)
- Should Inventor(s) choose to continue to develop the technology it would be without CCIV support
- Inventor(s) may submit a new disclosure when additional information or data is available to be reconsidered

How CCIV determines the disposition

Categorization

- Portfolio
 Manager and
 Inventor(s) to
 consider a
 development
 path based on a
 template
 depending on
 Inventor(s)
 interest
- Additional CCIV or external expertise may be sought

Stage Assessment

- Portfolio
 Manager and
 Inventor(s) to
 assess what
 stage of
 development the
 asset is at within
 the selected
 category
- Additional CCIV or external expertise may be sought

Info Assessment

- Portfolio
 Manager and
 Inventor(s) to
 determine if there
 is enough
 information on
 hand to know the
 next
 development
 step
- Additional CCIV or external expertise may be sought

Disposition determination based on Criteria

- Inventor(s)Driven
- Shared Responsibility
- Not pursued



Criteria Considered During Disposition

- Is there clinical utility? What would the impact of this invention be if brought to the market?
- What is the relative advantage of the technology as compared to what we know is on the market or in development pipelines?
- Protectability of the competitive advantage (i.e., patentability, copyright, exclusive data)
- Is there a path to development? Is the investigator planning to continue to work on the tech? Are we aware of commercial partners that may exist?
- Feasibility of the tech based on current data
- Market Trends to our knowledge
- Regulatory pathway feasibility based on our experience



Input from CCIV Co-CSOs

 Inventor(s) have the right to appeal the disposition decision to the CCIV co-CSOs

• If co-CSOs overturn Innovation Ventures' disposition decision, the technology shall follow the standard management process as outlined in this document



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Disclosure Reporting & Assessment

• ≤ 30 days of disclosure submission

Review Process & Disposition

• ≤120 days of meeting with Inventor(s)

MANAGEMENT

Initial Commercial Strategy

> ≤ 30 days of Review Process & Disposition

Intellectual Property Management

> Timelines determined by patent offices

Marketing

 Ongoing once technology reaches "Marketing" status Agreement Due
Diligence, Negotiation,
& Execution

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Initial Commercial Strategy

(Inventor(s) Driven)



Intellectual Property

Management



Marketing



Agreement Due Diligence, Negotiation, & Execution

Inventor(s)

≥30 days prior to public disclosure

 Provide update to Innovation Ventures before any public disclosure (e.g., dissertation, abstract submission, poster presentation, presentation outside of internal division, publication submission, discussion outside of immediate collaborators, etc.)

≤ 30 days of an Innovation Ventures request

See <u>IP Management process</u>

On an ongoing basis

- Apply to opportunities that may advance the technology:
 - Existing programs identified by Innovation Ventures
 - Other funding opportunities or collaborations with complementary expertise

Innovation Ventures

≤ 30 days of Review Process & Disposition

- Determine who the Inventor(s) are based on the IP policy, and gain initial alignment on any revenue split should the invention be commercialized
- Deliverable:
 - Align on next steps within a template development path
 - Determine whether registration of a Copyright or filing of a non-provisional Patent is warranted

On an ongoing basis

- Identify partner matches that may help advance the technology
- Check-ins with Inventor(s) on progress every 6 months
- Check-ins with Inventor(s) when IP input is needed

Initial Commercial Strategy

(Shared Responsibility)



Intellectual Property

Management



Marketing



Agreement Due Diligence, Negotiation, & Execution

Inventor(s)

≥ 30 days prior to public disclosure

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≤ 30 days of an Innovation Ventures request

See <u>IP Management process</u>

On an ongoing basis

- Advise on proposed development steps
- Receive feedback on development steps from Innovation Ventures, and Innovation Ventures's advisors and industry contacts
- To the extent resources are available, perform commercially relevant experiments
- Apply for funding that will further the commercial development of the invention
- A clear indication as to what extent the Inventors' desire to continue to work with the industry partner after a potential industry agreement
- Commitment to be willing to serve on an Innovation Ventures committee

Innovation Ventures

≤ 30 days of Review Process & Disposition

- Determine who the Inventor(s) are based on the IP policy, and gain initial alignment on any revenue split should the invention be commercialized
- Review potentially competitive products
- Search of patent/publication literature
- <u>Deliverable:</u>
 - Begin to discuss and align on development steps based on a template development path
 - Determine whether registration of a Copyright is warranted or determine the scope of non-provisional Patent claims

On an ongoing basis

- Seek input from internal and external advisors
- Active IP assessment
- Attempt to match to sources of development funding
- Identify the development steps that will move the invention to a commercial endpoint

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MANAGEMENT

Initial Commercial Strategy

• ≤ 30 days of Review Process & Disposition Intellectual Property Management

> Timelines determined by patent offices

Marketing

 Ongoing once technology reaches "Marketing" status Agreement Due Diligence, Negotiation, & Execution

- Timeline determined by partner
- Innovation Ventures to follow up every 2 weeks



Intellectual Property Management



Marketing



Agreement Due Diligence, Negotiation, & Execution

Inventor(s)

≥ 30 days prior to public disclosure

 Provide update to Innovation Ventures before any public disclosure (e.g., abstract submission, poster presentation, presentation outside of internal division, publication submission, etc.)

≤ 30 days of an Innovation Ventures request

- Provide Innovation Ventures and external patent counsel with written information related to the invention, as directed by patent manager and portfolio manager
- Availability for ongoing in-person or teleconference meetings
- Complete and sign documents necessary for the patent process
- An invention disclosure if one does not exist on what is being filed, as determined by Innovation Ventures

Innovation Ventures

In compliance with legal deadlines

- Determine inventorship based on patent law
- Determine commercially relevant scope of protection
- Assign and work closely with external patent counsel and cover related costs
- Work with other co-owners or organizations with 3rd party rights
- Report IP progress to sponsors, if relevant

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Intellectual Property

Management



Marketing (Shared Responsibility)



Agreement Due Diligence, Negotiation, & Execution

Inventor(s)

≤ 14 days of an Innovation Ventures request

- Inform Innovation Ventures of any industry or investor that they meet or are aware of that may be interested in the invention
- Review drafts of non-confidential marketing materials
- Provide Innovation Ventures with updated data and information relevant to the invention
- Availability for non-confidential, and confidential meetings with industry, as specified by Innovation Ventures

Innovation Ventures

Ongoing basis after market readiness criteria are met

- Set marketing strategy and timeline based on status of invention
- Draft non-confidential marketing materials, if necessary
- Clarify to inventor(s) what materials are non-confidential and what are confidential
- Make non-confidential materials available via Innovation Ventures website, marketing campaigns, partnering meetings, and/or Innovation Ventures connections, as determined by Innovation Ventures
- Perform Denied Party Screenings on foreign entities
- Encourage industry/investors to proceed to enter into a confidentiality agreement



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MANAGEMENT



Initial Commercial Strategy

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Intellectual Property Management

> Timelines determined by patent offices

Marketing

 Ongoing once technology reaches "Marketing" status Agreement Due Diligence, Negotiation, & Execution

- Timeline determined by partner
- Innovation Ventures to follow up every 2 weeks

Initial Commercial Strategy



Intellectual Property

Management



Marketing



Agreement Due Diligence, Negotiation, & Execution (Shared Responsibility)

Inventor(s)

≤ 14 – 30 days of an Innovation Ventures request

- Availability for meetings with the industry partner and with Innovation Ventures
- Provide feedback to Innovation Ventures of the potential partner
- Consider appropriateness of development path of potential partner
- A specific, written summary of technical know-how to be transferred under the agreement
- A scope of work, if one is called for under the agreement, and budget to be approved by division business contact
- Resolve any conflict of interest or conflict of commitment issues, if needed

Innovation Ventures

Upon interest from industry or investor interest in entering into an agreement for development and/or commercialization

- Assess whether the partner is an appropriate match for the invention
- Negotiate term sheet
- Provide notice to CCHMC conflict committee/Legal/ORCRA/ Div. Dir./SRS of potential COI, as appropriate
- Keep faculty informed of negotiation, and potential impacts on them as a result of the agreement
- Work with internal or external counsel, as necessary, to negotiate and execute agreement



Moving a Project into Acceleration



Shared Responsibility Management process steps hold true whether an invention is in Portfolio Management or Acceleration.

If an invention moves into Acceleration, it may occur at various points during Shared Responsibility Management.

HOW INVENTIONS MOVE INTO ACCELERATION



Review Process

Innovation Ventures & External Expertise (as needed)

Project reviews will be presented to the evaluation committee consisting of Innovation Ventures Leadership, with the outcome communicated to the inventor(s) thereafter.

Expectations

Acceleration requires a higher level of commitment from both Inventor(s) and Innovation Ventures.



Ongoing Assessment and Right-Sizing the Portfolio



Transitioning to this SLE

- In order to meet the commitments of this document, we need to review the existing portfolio through this lens
- This transition to review the old portfolio will take time

 Over the 2023 fiscal year we will be implementing a plan to review the existing portfolio through the lens of our new process and criteria



Technologies in the portfolio will be assessed on an ongoing basis by these criteria

- Is there clinical utility? What would the impact of this invention be if brought to the market?
- What is the relative advantage of the technology as compared to what we know is on the market or in development pipelines?
- Protectability of the competitive advantage (i.e., patentability, copyright, exclusive data)
- Is there a path to development? Is the investigator planning to continue to work on the tech?
 Are we aware of commercial partners that may exist?
- Feasibility of the tech based on current data
- Market Trends to our knowledge
- Regulatory pathway feasibility based on our experience
- Market interest / Feedback from potential licensees
- Responsiveness of the Inventor(s) to CCIV request as outlined throughout the stages



Changing the Disposition of a Technology

- During the course of development, if the assessment of the technology changes, there will be a meeting with the Inventor(s) to discuss the following:
 - The current assessment based on the criteria
 - An estimate of costs expended on the technology to date
 - A determination of the updated disposition
- CCIV continually will seek alignment from the Inventor(s) on disposition decisions. If the Inventor(s) are non-responsive, CCIV will make the decision using its best judgement
- Inventor(s) have the right to appeal the disposition decision to the CCIV co-CSOs, if Inventor(s) indicate their desire to appeal within 15 days of a deadline provided by CCIV



2. Sending and Receipt of Biologic and Copyright Research Tools



Biologic Research Tool Expectations Overview

	Researcher	Sponsored Research Services (SRS)	Innovation Ventures	Legal
•	If sending materials:Submit a complete RT disclosure via the	 Manages agreements submitted through the Huron Agreement portal 	 Within 3 days of an RT disclosure submission, an acknowledgement of receipt will be sent 	Reviews uncommon legal
	 Inventor Portal, and respond to any requested missing information If sending to a: 	 Responsible for review and negotiation of agreements related to: Any materials being received from another organization 	 Within 30 days of RT disclosure submission, will assess any restrictions that may exist in sending the materials and communicate these to SRS, if needed 	provisions in agreements
	 Not-for-profit organization, then create a Huron (HRS) Agreement 	 Materials being sent to a not- for-profit organization Requests guidance from the 	 Responsible for negotiating reasonable financial provisions and agreements to send materials to for-profit organizations 	direction on the sending of clinical materials
	<u>record</u>For-profit organization, then	Researcher on terms that may impact research or publication	 Provides guidance to SRS regarding Intellectual Property provisions 	and data
	contact Innovation Ventures If receiving materials	 Requests guidance from Innovation Ventures on Intellectual Property terms 	 Requests guidance from the Researcher on terms that may impact research or publication 	
	regardless of the type of organization, create a <u>Huron</u> (HRS) Agreement record	 Requests guidance from Legal for uncommon provisions and the 	 Requests guidance from Legal for uncommon provisions 	
•	Respond to any questions from Innovation Ventures and/or SRS	sending of clinical materials and data	 Clinical materials and data generally not provided to for-profit entities 	

Copyright Research Tool Expectations Overview



	Researcher		Innovation Ventures		Legal	
•	Submit a complete RT disclosure via the Inventor Portal , and respond to any requested missing information	•	Within 3 days of an RT disclosure submission, an acknowledgement of receipt will be sent	•	Reviews uncommon legal provisions in agreements	
•	Contact Innovation Ventures		Within 30 days of RT disclosure submission, will assess any restrictions that may exist in sending the materials	•	Provides direction on the sending of clinical data	
•	Respond to any questions from Innovation Ventures		Responsible for negotiating reasonable financial provisions and agreements to send materials to for-profit organizations			
		•	Responsible for review and negotiation of agreements			
		•	Requests guidance from the Researcher on terms that may impact research or publication			
		•	Requests guidance from Legal for uncommon provisions			
		•	Clinical data generally not provided to for-profit entities			

3. Sponsored Research



Sponsored Research Expectations Overview

	Researcher		Sponsored Research Services (SRS)		Innovation Ventures		Legal
•	Create a <u>Huron (HRS)</u> <u>Agreement record</u>	•	Manages agreements submitted through the Huron Agreement portal	•	Provides guidance to SRS regarding Intellectual Property provisions	•	Reviews uncommon legal
•	Work with the Sponsoring Company on the scope of work	•	Responsible for review and negotiation of Sponsored Research Agreements	•	Requests guidance from the Researcher on terms that may impact research or publication and provides input to Researcher on how this agreement may impact future work		provisions in agreements
•	Work with your Financial Analyst/Manager or Business Manager/Director on the budget	•	Requests guidance from the Researcher on terms that may impact research or publication	•	Requests guidance from Legal for uncommon provisions		
•	Respond to any questions from Innovation Ventures and/or SRS	•	Requests guidance from Innovation Ventures on Intellectual Property terms	•	Clinical materials and data generally not provided to for-profit entities		
•	Submit a complete Invention Disclosure if Innovation Ventures determines there is relevant background intellectual property	•	Requests guidance from Legal for uncommon provisions				