Building an Effective Export Control Program within an Evolving Research Environment

**Nationwide Children's Hospital
& Abigail Wexner Research Institute**

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NATIONWIDE CHILDREN'S HOSPITAL

1.5 Million Patient Visits

A global referral destination with patients
from all 50 states and more than 50 countries
worldwide.

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ABIGAIL WEXNER RESEARCH INSTITUTE

2021 EXTERNAL AWARDS

FUNDING IN MILLIONS BY SOURCE

Program	$1.4	
Industry	$15.2	
Other	$29	
Federal Other	$37.5	
NIH Prime	$51.8	

2021 $134.9

RESEARCH BY THE NUMBERS

	2019	2020	2021
Principal Investigators*	207	208	223*
Research Fellows	71	71	92
Graduate Students	38	42	57
Employees	1583	1534**	1460
Publications	1357	1600	1633

*Includes faculty from the Abigail Wexner Research Institute and faculty from Nationwide Children's Hospital with $50,000 or more in research funding support.

**In 2020, Andelyn Biosciences became a separate entity, resulting in approximately 100 employees moving from Nationwide Children's to Andelyn Biosciences.

One of three research buildings; fourth building to open in Spring 2023

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International Collaborators

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Do you know the state of your Export Control Program?

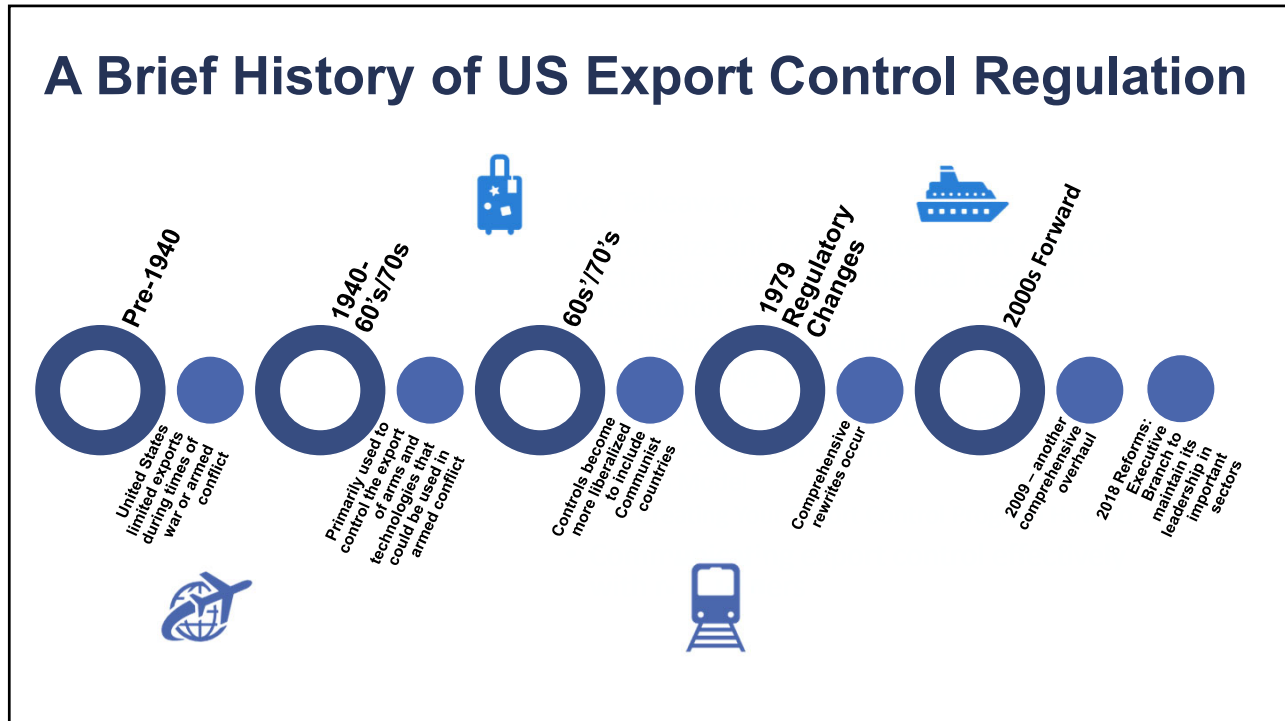|	
	What drew you to attend today's session?
	Do you know your portfolio?
	Have a policy?
	Have a resource?
	Anyone performing screenings?

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Building an Effective Export Control Program

Key Takeaways:
- Strategize and coordinate export control activities within a biomedical research institution
  - Brief History and Primer on Export Control
  - Performing a Risk Assessment
- Define key components of an effective export control program
  - BIS Model
  - Creating Your Export Control Program How-To
- Communicating export controls effectively with researchers
- Fundamental Research Exclusion

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A Brief History of US Export Control Regulation

Pre-1940
United States limited exports during times of war or armed conflict

1940-60's/70s
Primarily used to control the export of arms and technologies that could be used in armed conflict

60s'/70's
Controls become more liberalized to include Communist countries

1979 Regulatory Changes
Comprehensive rewrites occur

2000s Forward
2009 – another comprehensive overhaul

2018 Reforms: Executive Branch to maintain its leadership in important sectors

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Important Agencies

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Export Control in a...

3 Kinds of considerations:

- **Technology/Goods** restrictions
- **Country** restrictions
- **People** and **entity** restrictions

Exports can be illegal because of:

- **What** it is
- What **country** it's going to
- The **recipient** individual and Institution (US or out of country)
- End **use**
- Suspicion of **third-party** transfer

If your work involves…

- ✓ International contact
- ✓ International travel
- ✓ Receiving or transferring restricted material
- ✓ Restricted participation
- ✓ Restrictions on publication
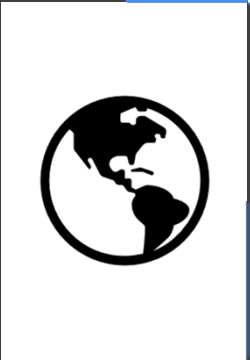
…then your work involves Export Controls!
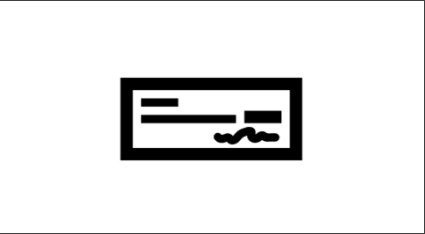
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Why Are Export Controls Important To You?

Know Your Business, Obligations, and Risk Areas

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What Types of Activities are Affected by Export Control?

Export Control Considerations

International Travel and Presentations

Foreign Nationals in the Workforce

International Shipping

Use of Restricted Materials in Research

International Collaborators

Financial Transactions

Training Resources

Policy and Procedures

Screening Against Sanction Databases

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5 Years Ago…

We didn't even have on our radar the idea that:

- Materials being sent to collaborators in foreign countries must be screened first
- A foreign national should not have access to export-controlled materials without an export license
- Researchers traveling abroad cannot take export-controlled materials, data, or information with them without screening first

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Find a Friend!

Interview Export Control Programs

- Reach out to others who have started the process to learn from them

- Leverage your existing relationships with other institutions
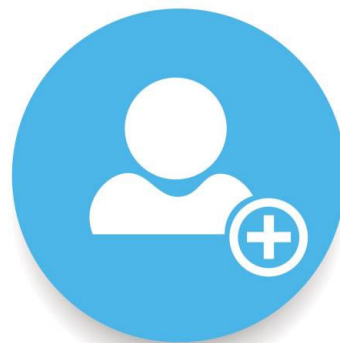
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Now That You Know What You Don't Know…

IT'S TIME TO IDENTIFY YOUR ORGANIZATIONAL NEEDS

KEY STAKEHOLDER BUY IN IS CRUCIAL

OPERATIONAL EXPERTS WILL BE YOUR BEST FRIENDS TO IDENTIFY GAPS

GAP ANALYSIS ROUTE

NCH: RISK ASSESSMENT ROUTE

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Who is Steering the Risk Assessment Ship?

- Internal Audit
- Compliance
- Legal Services
- Outside Consultant

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Performing an Export Controls Risk Assessment

📋	Evaluate current processes
👥	Interview key personnel and operations members
🔍	Identify the risks
🧠	Put together findings for leadership
👥	Work within organization to remediate findings

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What NCH Learned From the Process:
Compliance Without a Coordinated Program

- We lacked a policy outlining expectations and requirements for the organization
- There was no formal tracking mechanism, recording location, or resource
- Relied on individuals for knowledge of a process, no formal processes

Without a
COORDINATED PROGRAM
things could
SLIP THROUGH THE CRACKS

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Compliance Without a Coordinated Program

- We did not have a way to assess compliance risk
- We did not have a mechanism for tracking or recording determinations
- We did not have a centralized resource for communication, education, and assistance

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Bureau of Industry and Security Recommendations

Management Commitment

Risk Assessment

Export Authorization

Recordkeeping

Training

Audits

Handling Export Violations and Corrective Actions

Build and Maintain Your Export Control Manual

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Getting Off the Ground: Creating Your Export Control Program

1. Who is the Captain?
   Importance of Sponsors or Executive Champions

2. Who is Steering the Ship?
   Project Management Essentials

3. Where's the Crew?
   Benefits of having Focus Groups

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Who is the Captain?

Obtaining an Executive Sponsor	Liaison with Leadership Helps to Obtain Approval for Changes

Identify Essential Departments for your Project	Compliance Legal/Risk Management Operational Areas

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Project Management

✓ **Someone to manage and be point person**

✓ **Set goals, set regular meetings to meet those goals**

✓ **Create groups of responsible parties**

✓ **Provide regular updates on progress to leadership, and identify the items that will require leadership approval prior to moving forward**

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Focus Groups/Working Groups

"Bucket" Method

Identify Leaders for Each "Bucket"

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Export Control "Buckets" at NCH

Materials

International Travel

Finance

People

Data & Devices

Next Steps

COMPREHENSIVE POLICY

DESIGNATED EXPORT CONTROL PERSONNEL

MONITORING PROCESS

TOOLS OF THE TRADE

Create a Comprehensive Policy

A policy should spell out:

- Rules of the Road for Employees
- Training and Resources
- Record Keeping
- Auditing and Monitoring

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Provide an Export Control Resource

- "Go To" person for questions, needs, etc.
- Dedicated source for education
- Can continue the ongoing work of coordinating your program
- Works through issues as they arise
- Manages required screenings

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Monitoring Processes

Ensuring the controls you put in place are working and that individuals are following policy.

Tools of the Trade

Don't think you have to do it all alone!

There are resources and systems that can help – whether homegrown or out-of-the-box.

Ongoing Activities to Minimize Risk

- Create a Plan
- Systematic and Ongoing Portfolio Evaluation
  - Know your business
- Stay Connected with Organization
  - Export control issues can come from anywhere
- Monitor Activities
- Communicate Often

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Fully Integrated Export Control Communications

Inform Entire Institution of Upcoming Policy and Rule Changes	Message Directly to Key Individuals: Center Directors, Managers
Direct Education to Administrative Staff, Research Associates	Focus on Easy-To-Use Materials, Tools

Make it Easy to Comply!

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Communicating Export Control Requirements to Various Audiences

Ground floor Meetings

- Administrative Assistants
- Hazardous Material Shipping Training
- Each Center of Excellence

C-Suite Meetings

- Integration into Standing Center Directors Meetings
- Taught Research Administration First

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Where To Go From Here

Fundamental Research Exclusion

NSPM 33

Emerging Technologies

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Fundamental Research: What it Means

As defined in the regulations, "Fundamental Research" includes **basic** or **applied** research in science and/or engineering where the resulting information is ordinarily published and shared broadly.

Basic research is driven by a scientist's curiosity or interest in a scientific question. To expand knowledge, not to create or invent something. No obvious commercial value to the discoveries that result from basic research.

Applied research is designed to solve practical problems of the modern world, rather than to acquire knowledge for knowledge's sake. One might say that the goal of the applied scientist is to improve the human condition.

Fundamental Research Exemption: What Is Covered
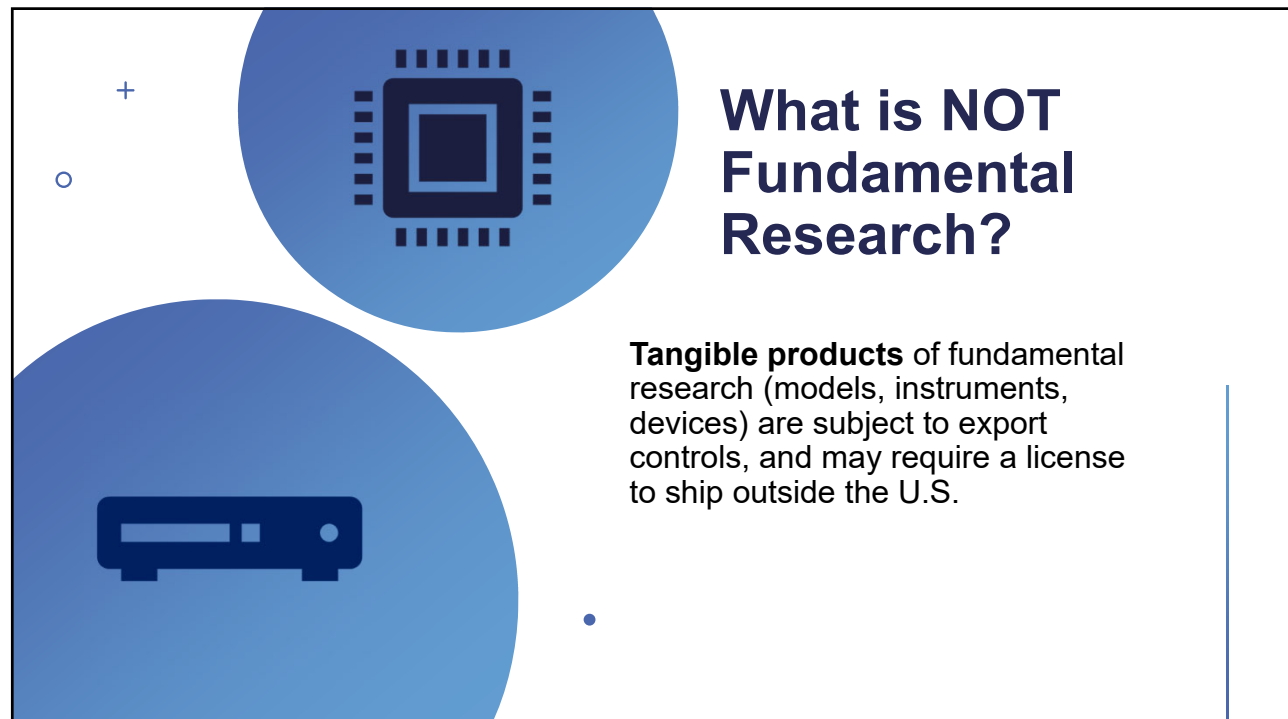
Everything in the United States except:
- Commodities and technology under other agencies' jurisdiction
- "Publicly Available" technology and software
- Information already published or will be published (15 CFR § 734.7)
- Technology that arises from fundamental research (15 CFR § 734.8)
- Educational (15 CFR § 734.9)
- Information included in patent applications (15 CFR § 734.10)

Fundamental Research Exclusion: What Impacts you

- The Fundamental Research Exclusion (FRE) provides that technology (meaning "technical data") or software that arises during, or results from, fundamental research and is intended to be published is excluded from the export control regulations.

✓ Sponsored Biomedical Research-case studies, analysis results, publications, grant submissions

❖ Intellectual property, restricted sharing of data

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What is NOT Fundamental Research?

Tangible products of fundamental research (models, instruments, devices) are subject to export controls, and may require a license to ship outside the U.S.

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What does this all mean to you?

- The Fundamental Research Exclusion is NOT a catch all rule that eliminates the need to follow Export Control Regulations
- Coordinated programs are more effective at reducing risk to your organization
- Research Security is fast becoming a reality for all involved in Research

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Evolving Flight Plan

"Emerging Technology" (ET)

- 2018 Notice of Proposed Rulemaking – 14 general areas/categories of emerging science/technology identified that may be essential to national security
- 38 ET Controls published to date – none directly related to biomedical research, however…opportunity exists for control in the future
  - (1) Biotechnology – Genomic and genetic engineering
  - (2) Artificial intelligence – Genetic algorithms, genetic programming
  - (11) Brain-computer interface – Neural-controlled interfaces
  - (14) Advanced materials – Biomaterials

**Challenge – More control or hands-off approach?**

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Beyond the Stratosphere: NSPM-33

NSPM-33, Memorandum on Security for U.S. Government-Supported Research and Development

- **Intent**
  - ✓ Strengthen protections of U.S. supported R&D against foreign government interference and misappropriation
- **Achieved by**
  - ✓ Funding agencies…Increasing and standardizing required disclosures of potential conflicts of interest
  - ✓ Research organizations…Certifying to the funding agency that you have established and operate a research security program
    - o Goal – Single certification standard and process that will apply across all research funding agencies
    - o Status – In progress; more information and guidance forthcoming
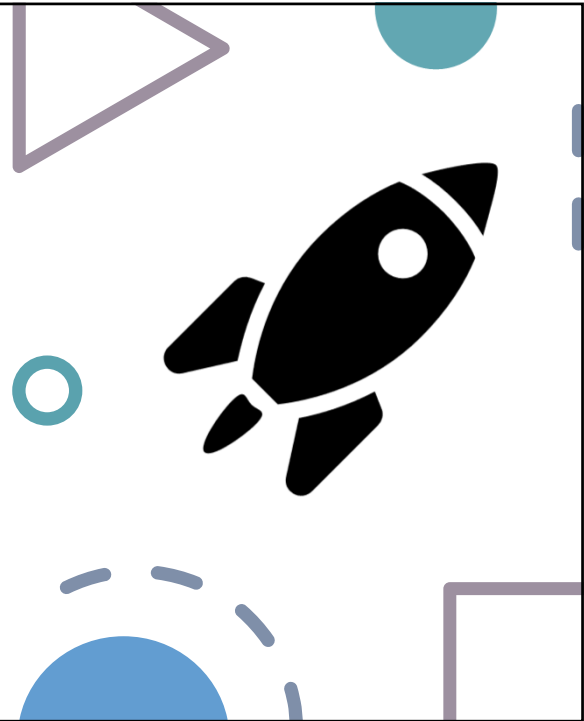
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Beyond the Stratosphere: Research Security Programs
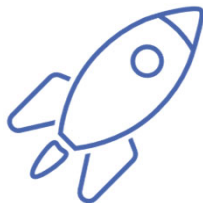
- Required for organizations receiving >$50 million in funding annually
- Four elements
  1) Cybersecurity
  2) Foreign travel security
  3) Threat awareness and identification training
  4) Export control training
- Compliance timeline – One year from the date the formal requirement is issued (pending)…but really, start now
- Discretion – Flexibility to leverage or integrate existing programs and activities, as long as all 4 elements are implemented
- Expectation –
  1) "Strongly encouraged" to have a "coherent" program
  2) Designate a point of contact that is "publicly accessible"
  3) Maintain a description of the program and be able to provide it within 30 days of a request

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Today's Key Take Away Points

If you don't know who manages Export Control at your Organization

Find Friends and Start the Conversation

If you are unsure how your Researchers ship or share data

Ask

Communication is key to reducing risk

Many Thanks to…

Thank You For Coming!

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