

TIPS AND TOOLS FOR IMPLEMENTING STANDARD 3

IDENTIFY, MITIGATE, AND DISCLOSE RELEVANT FINANCIAL RELATIONSHIPS

NICE TO MEET YOU!

TWO TRUTHS AND A LIE

Directions:

- Read each of the three statements in the poll.
- Determine which statement you think is a **lie**.
- Choose that option on the poll in the meeting.

Choice	Statement
A	I raise chickens
B	I love riding roller coasters
C	I have been a Zumba instructor

TWO TRUTHS AND A LIE - ANSWER

Directions:

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A	I raise chickens
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#fAVORITES

- Strategy Board Games
- Puzzles
- Harry Potter
- Nature
- Roller Coasters
- The Beach
- Gelato & Chocolate



A LITTLE ABOUT ME

- B.S. Animal Ecology
- M.Ed. Secondary Education
- Middle & High School Science Teacher for 15 years
- Instructional Coach
- eciccarelli@mainemed.com



CHECK-IN

On a scale of rubber duckies, how are you feeling today?

- Post your ducky number in the chat.

ACKNOWLEDGEMENTS

- MedScape – Basis of Flowchart
 - ACCME – Basis of Case Studies
-

OBJECTIVES

- Understand how to determine if a financial relationship is relevant
- Be able to select appropriate mitigation steps as necessary
- Utilize proper disclosure statements

How well do you know Standard 3?

Select all that apply on the poll.

STANDARD 3 – WHAT IS NEW/CHANGED?

- “Ineligible Companies” replaces “Commercial Interests”

INELIGIBLE COMPANIES

- **Definition:** Those whose primary business is producing, marketing, re-selling, or distributing healthcare products used by or on patients.
- These companies are deemed “ineligible” to be accredited in the ACCME System.

- Advertising, marketing, or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Reagent manufacturers or sellers

- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products
- Growers, distributors, manufacturers or sellers of medical foods and dietary supplements

- Compounding pharmacies that manufacture proprietary compounds
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers

STANDARD 3 – WHAT IS NEW/CHANGED?

- “Ineligible Companies” replaces “Commercial Interests”
 - Make sure the Faculty Disclosure Form uses the term “ineligible company” and includes a definition.
-

TWO TRUTHS AND A LIE

Directions:

- Read each of the three statements in the poll.
- Determine which statement you think is a **lie**.
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Choice	Statement
A	Faculty must disclose financial relationships for the past 24 months
B	Faculty do not need to disclose financial relationships of their spouse.
C	Faculty do not need to disclose a relationship if they received less than \$100.

TWO TRUTHS AND A LIE

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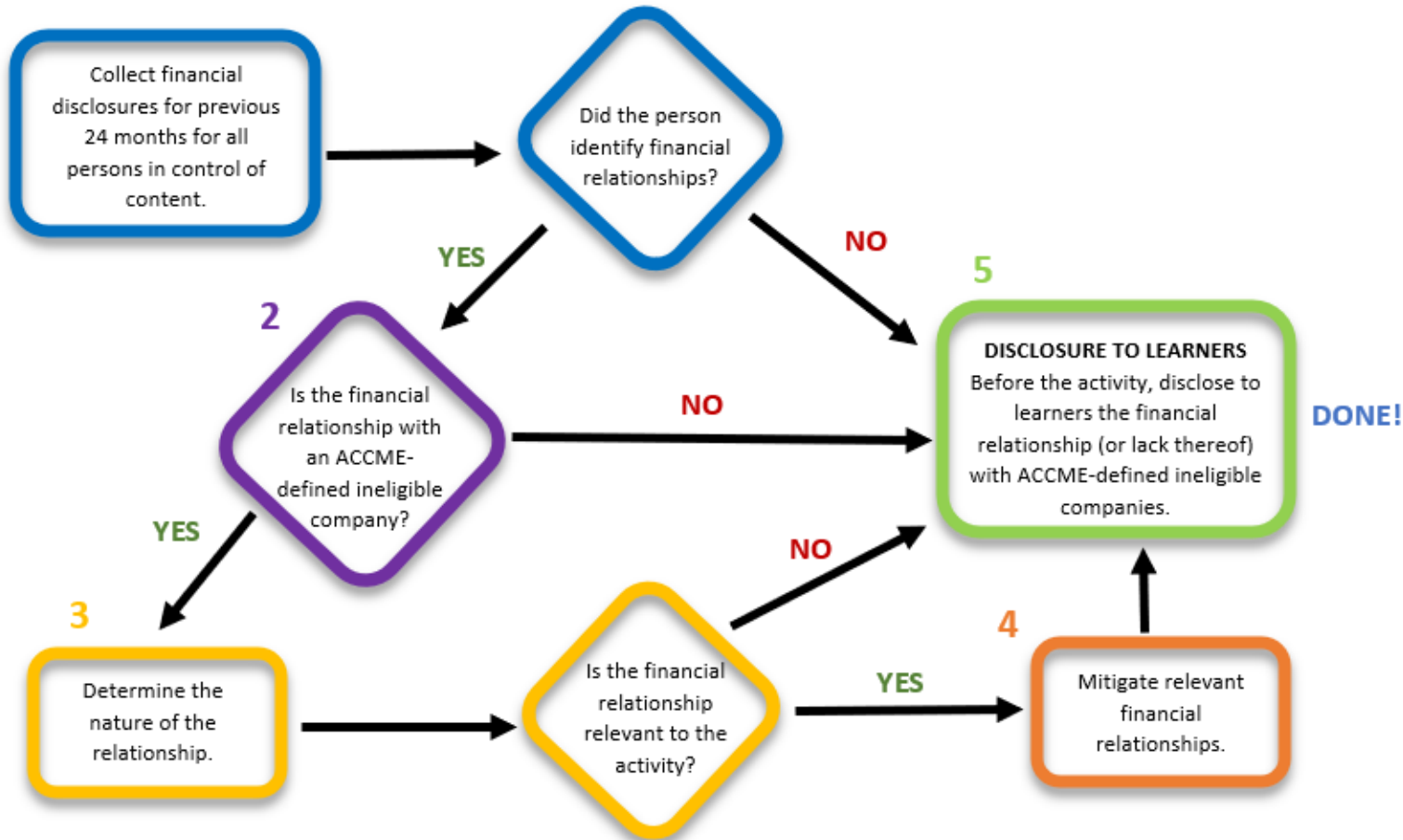
STANDARD 3 – WHAT IS NEW/CHANGED?

- “Ineligible Companies” replaces “Commercial Interests”
 - Make sure the Faculty Disclosure Form uses the term “ineligible company” and includes a definition.
 - Faculty must disclose ALL financial relationships with ineligible companies, regardless of the amount (there is no minimum threshold)
 - Disclosure period is for the prior **24 months** (used to be 12 months). Make sure this is indicated on the Disclosure Form
 - Spouse/Partner disclosure removed.
-

Meeting the Expectations of ACCME's Standard 3

1

Before you begin planning your education, collect information from ALL planners, faculty, steering committee members and others who would be in positions to control content.

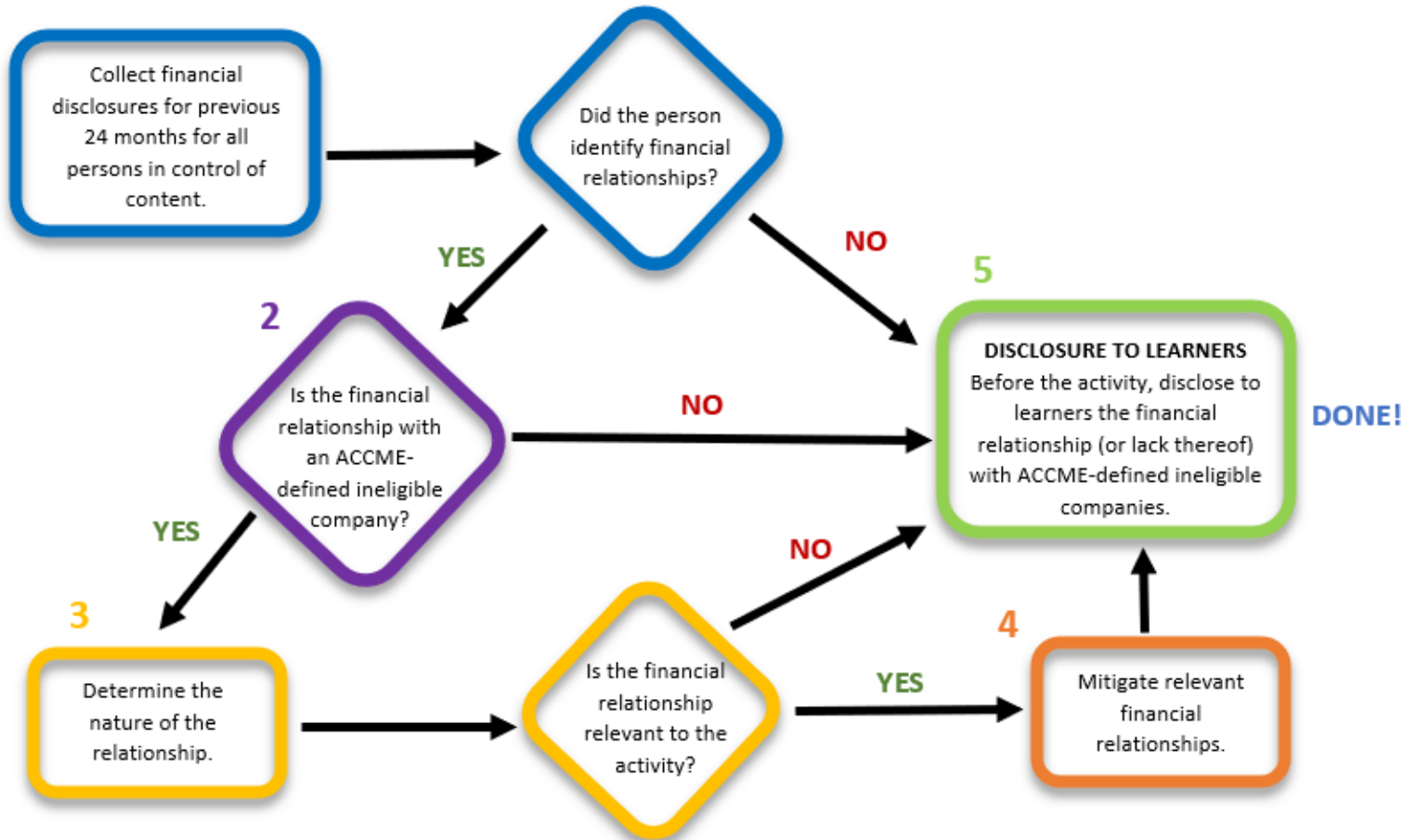


FLOWCHART FOR THE IDENTIFICATION, MITIGATION, AND DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

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1. Collect Faculty Disclosures

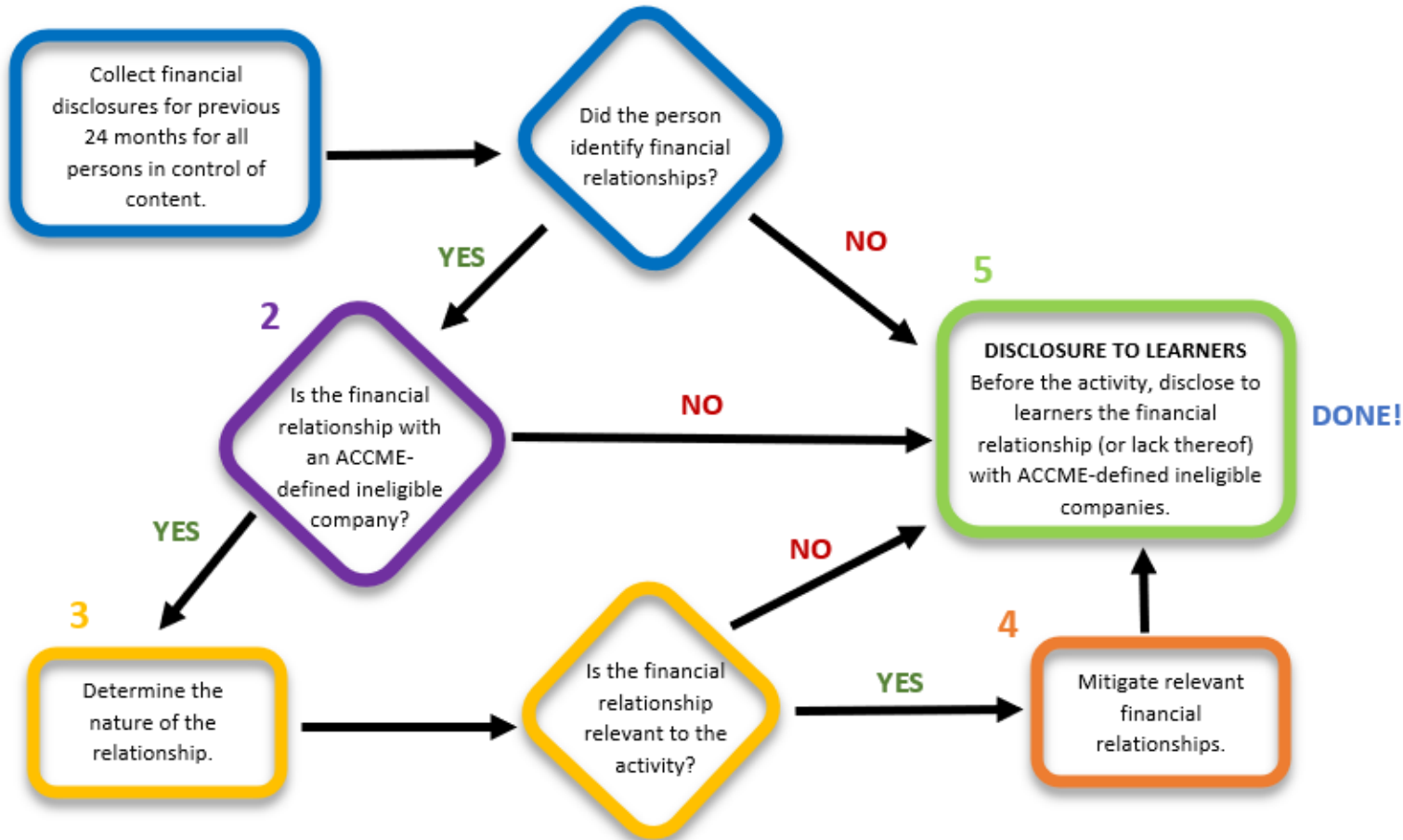
TIPS FOR IDENTIFYING RELEVANT FINANCIAL RELATIONSHIPS

- Nonclinical education does not require identification and disclosure of financial relationships.
 - *Providers/Planners* determine the relevance of the relationship to the education.
 - Relevance depends on the content an individual can control.
-

Meeting the Expectations of ACCME's Standard 3

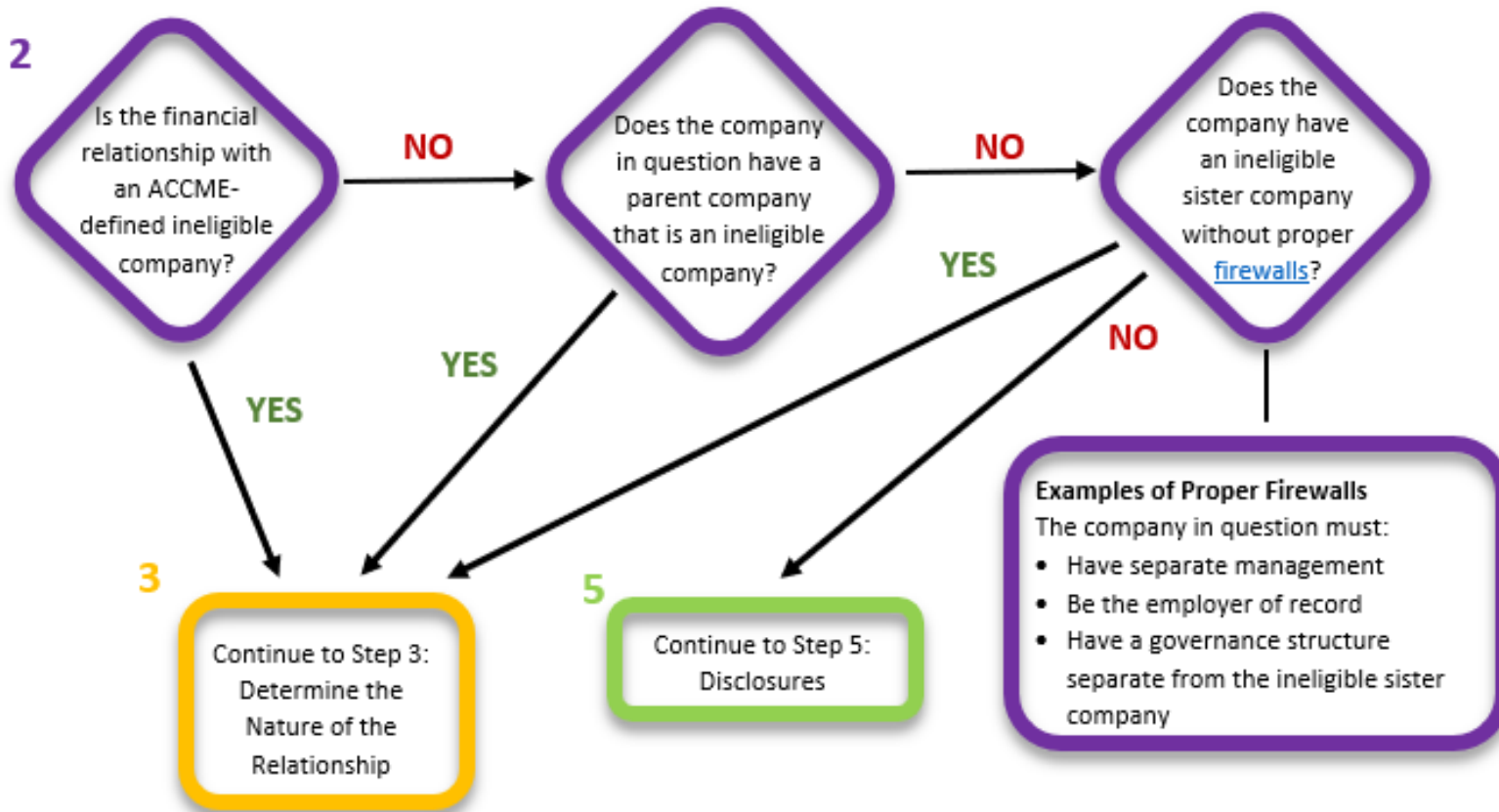
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FLOWCHART FOR THE IDENTIFICATION, MITIGATION, AND DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

2. Determine if the company is Eligible or Ineligible



FLOWCHART FOR THE IDENTIFICATION, MITIGATION, AND DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

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Eligible

- Ambulatory procedure centers
- Blood banks or infusion centers
- Diagnostic labs that do not sell proprietary products
- Electronic health record companies
- Government or military agencies
- Group medical practices
- Health law firms
- Health profession membership organizations
- Hospitals or healthcare delivery systems
- Insurance or managed care companies
- Nursing homes or rehabilitation centers
- Pharmacies that do not manufacture proprietary compounds
- Publishing or education companies
- Schools of medicine or health science universities
- Software game developers

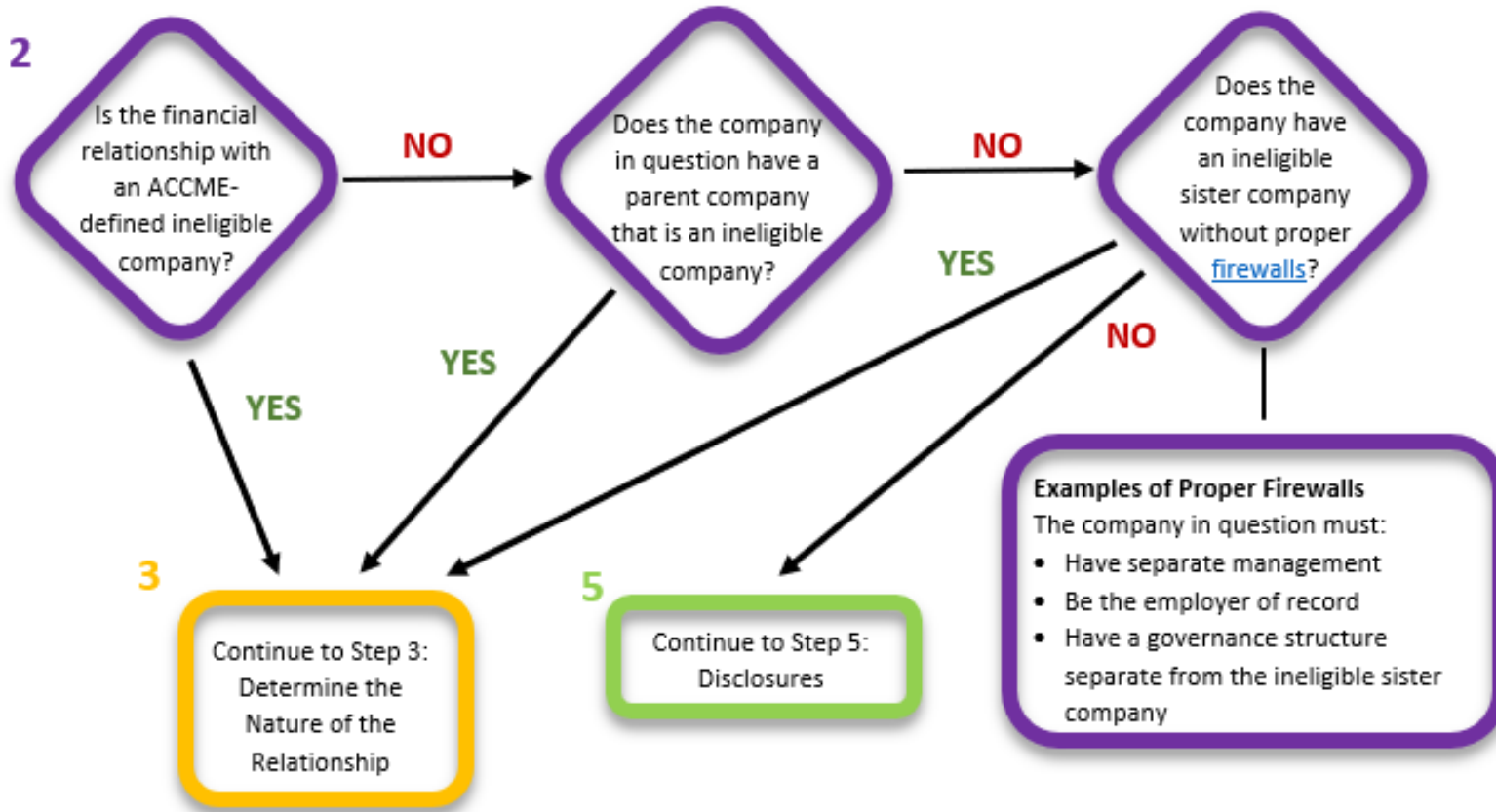
Ineligible

- Advertising marketing or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Compounding pharmacies that manufacture proprietary compounds
- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products
- Growers, distributors, manufacturers, or sellers of medical foods and dietary supplements
- Manufacturers or health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sellers
- A company or organization owned by any of the above

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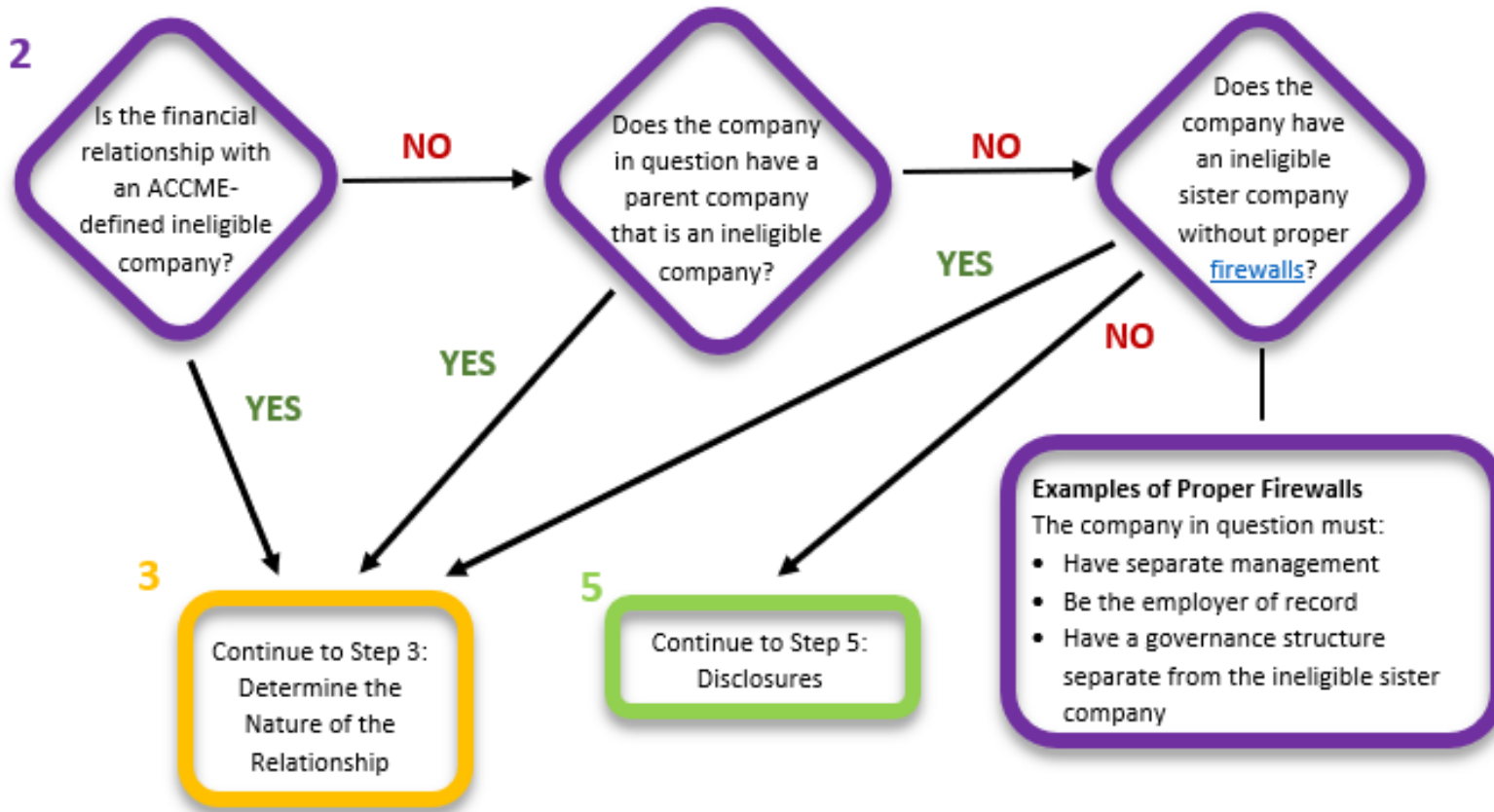
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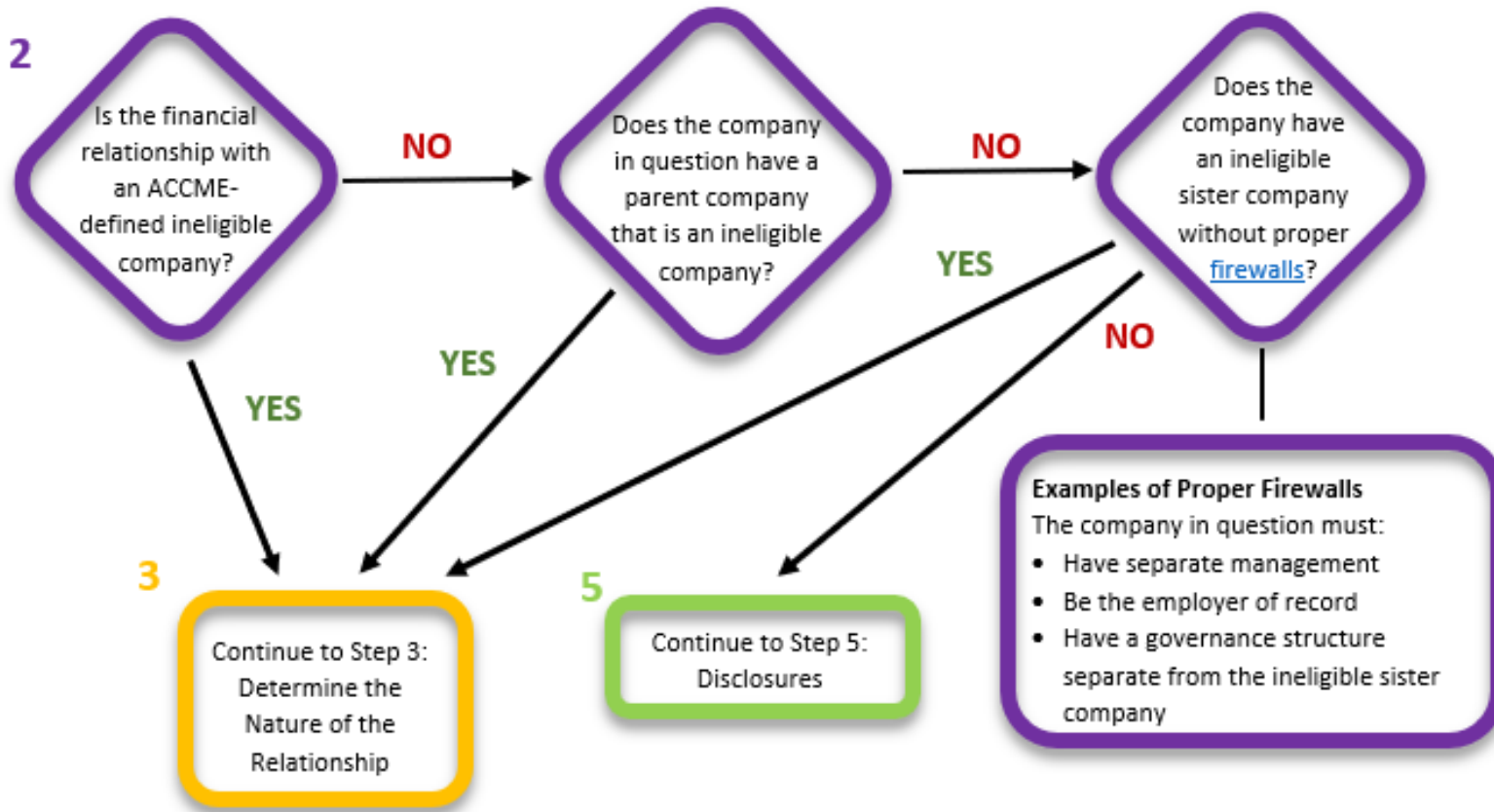
Sister Company: A separate legal entity which is a subsidiary of the same parent company that owns or fiscally controls an organization.

Johnson & Johnson

Holding company

Subsidiaries





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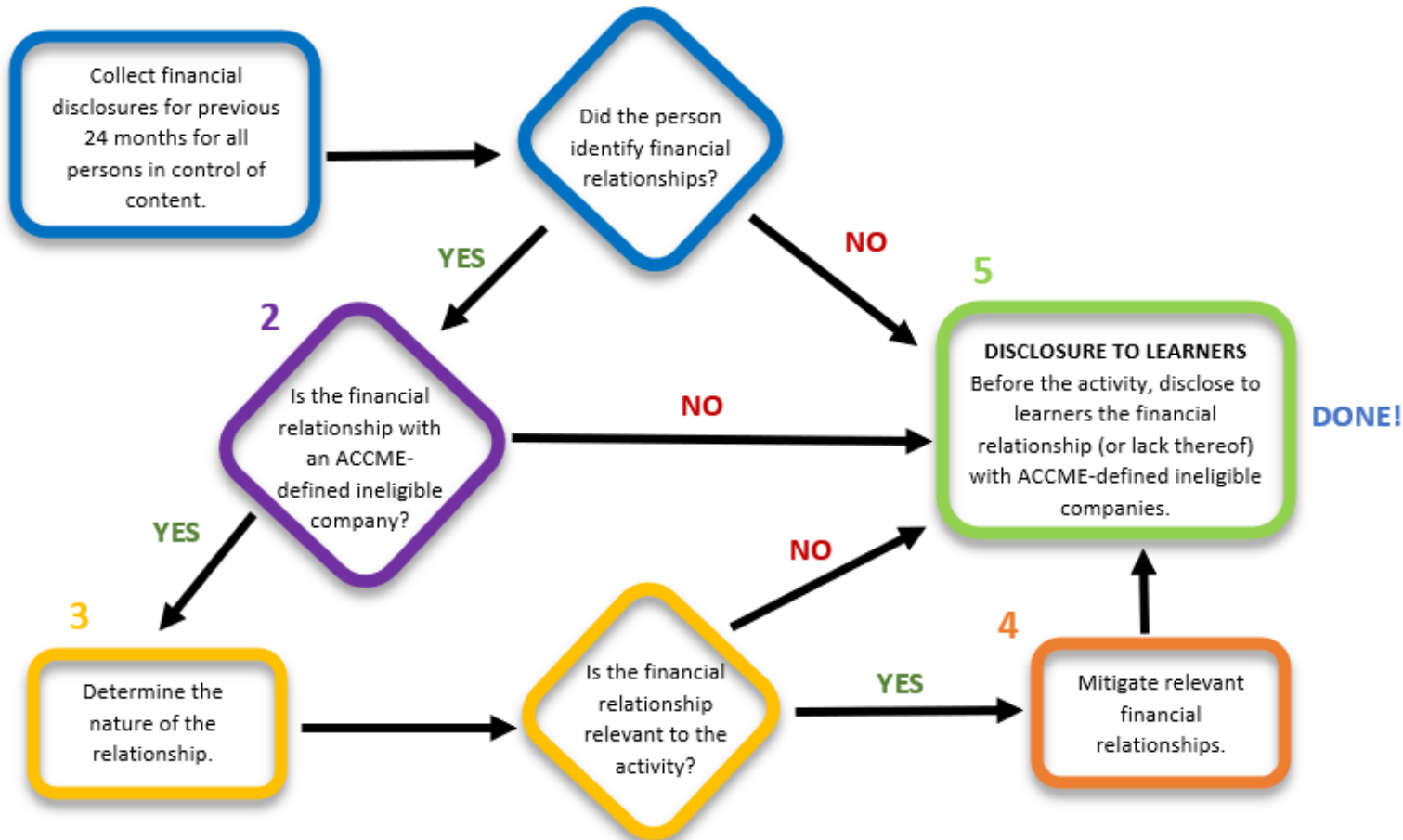
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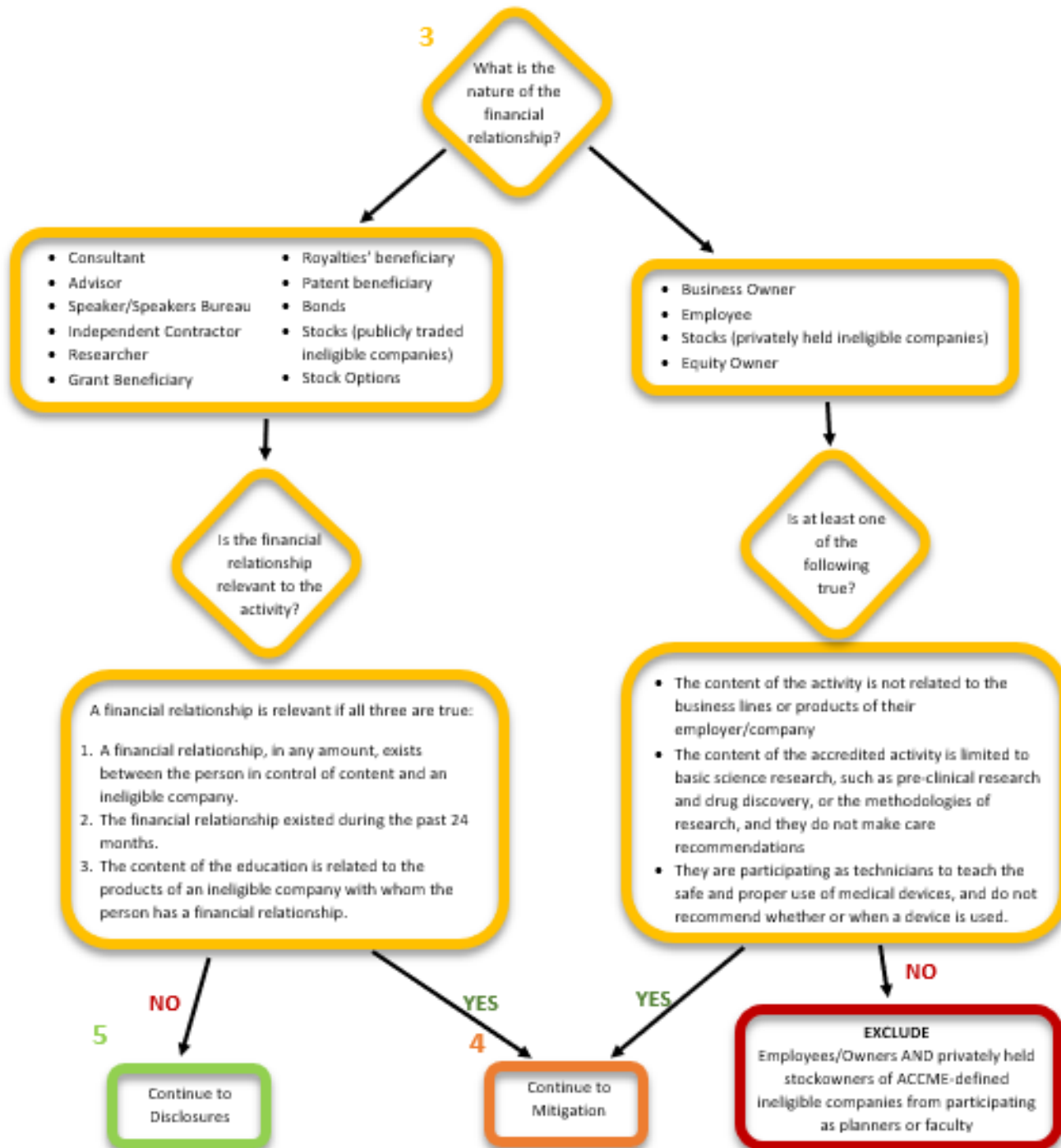


FLOWCHART FOR THE IDENTIFICATION, MITIGATION, AND DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

3. Determine the nature of relationship

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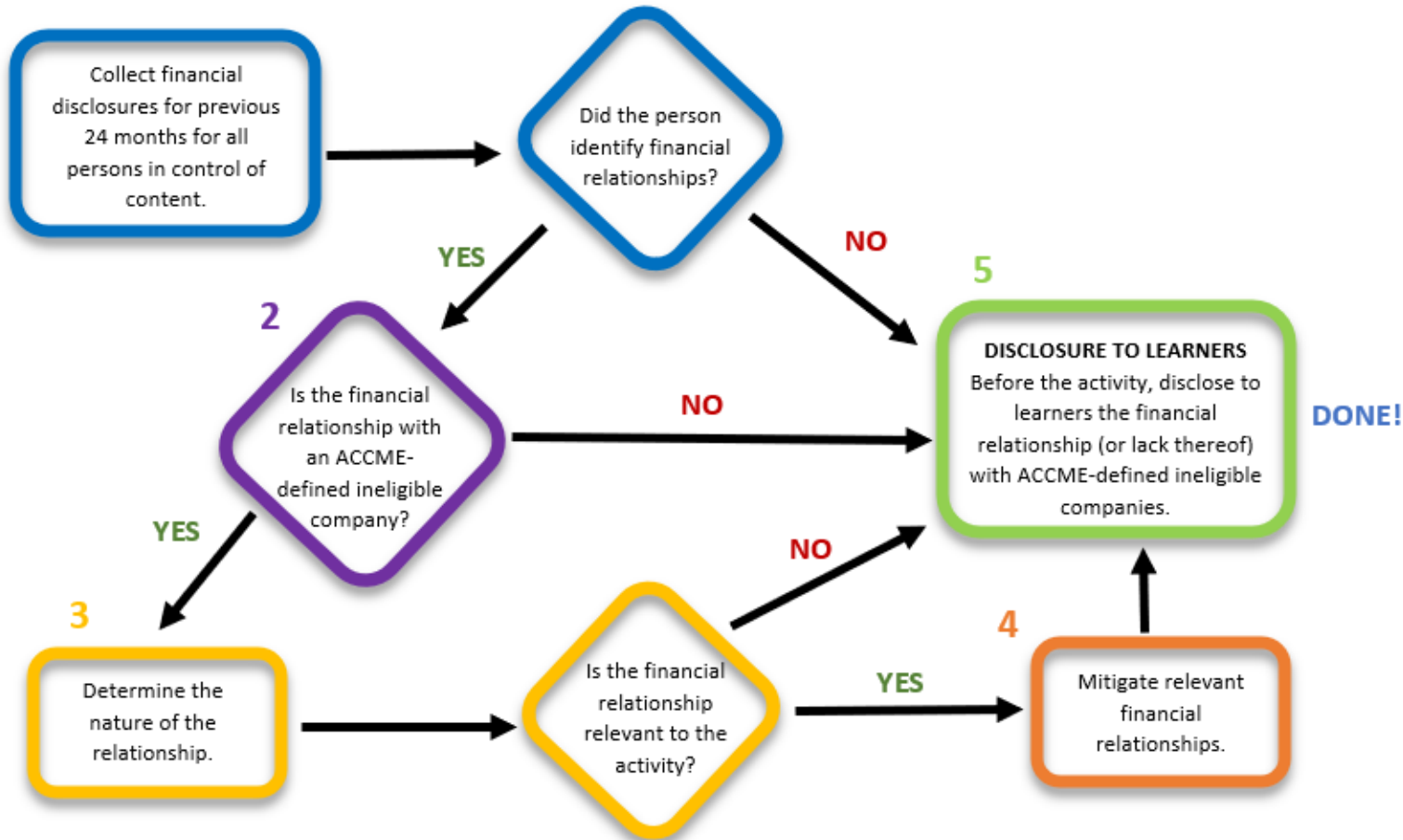
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FLOWCHART FOR THE IDENTIFICATION, MITIGATION, AND DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

4. Mitigate relevant financial relationships



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4. Mitigate relevant financial relationships

DOCUMENTING MITIGATION STEPS

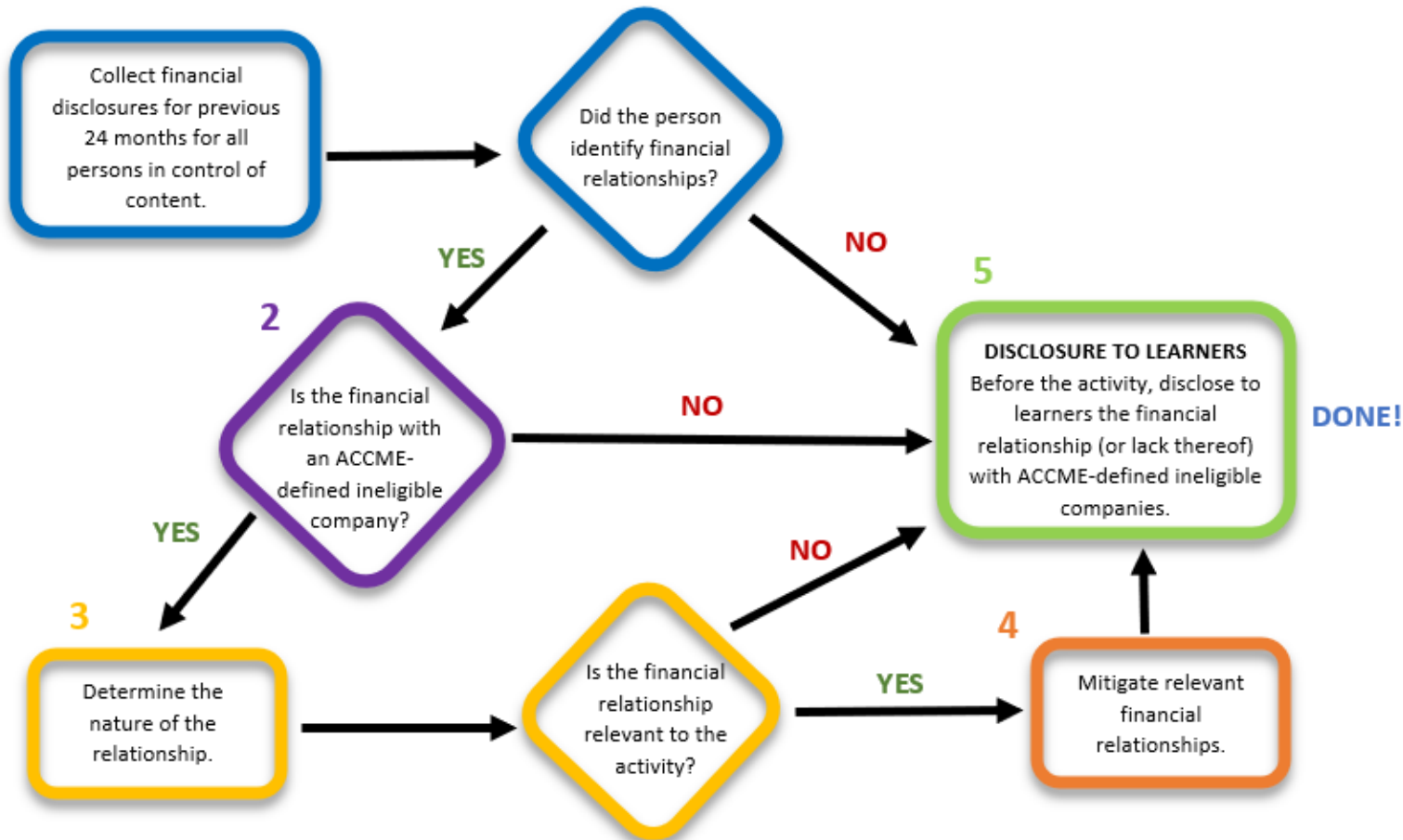
Mitigation Form				
Activity Name:				
Activity Date(s):				
<p>If any of the planners, presenters, or reviewers involved in the learning activity have any relevant financial relationships, complete this form to document how those relevant financial relationships were mitigated. These steps should be taken prior to planning and presenting. Submit this form along with the application materials.</p>				
Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(s)	Nature of Relationship(s)	Mechanism(s) Implemented to Mitigate Relevant Financial Relationships Appropriate to Role(s) in the Activity

- **MMET Consortium Members will be required to submit documentation of mitigation steps with their activities as applicable.**

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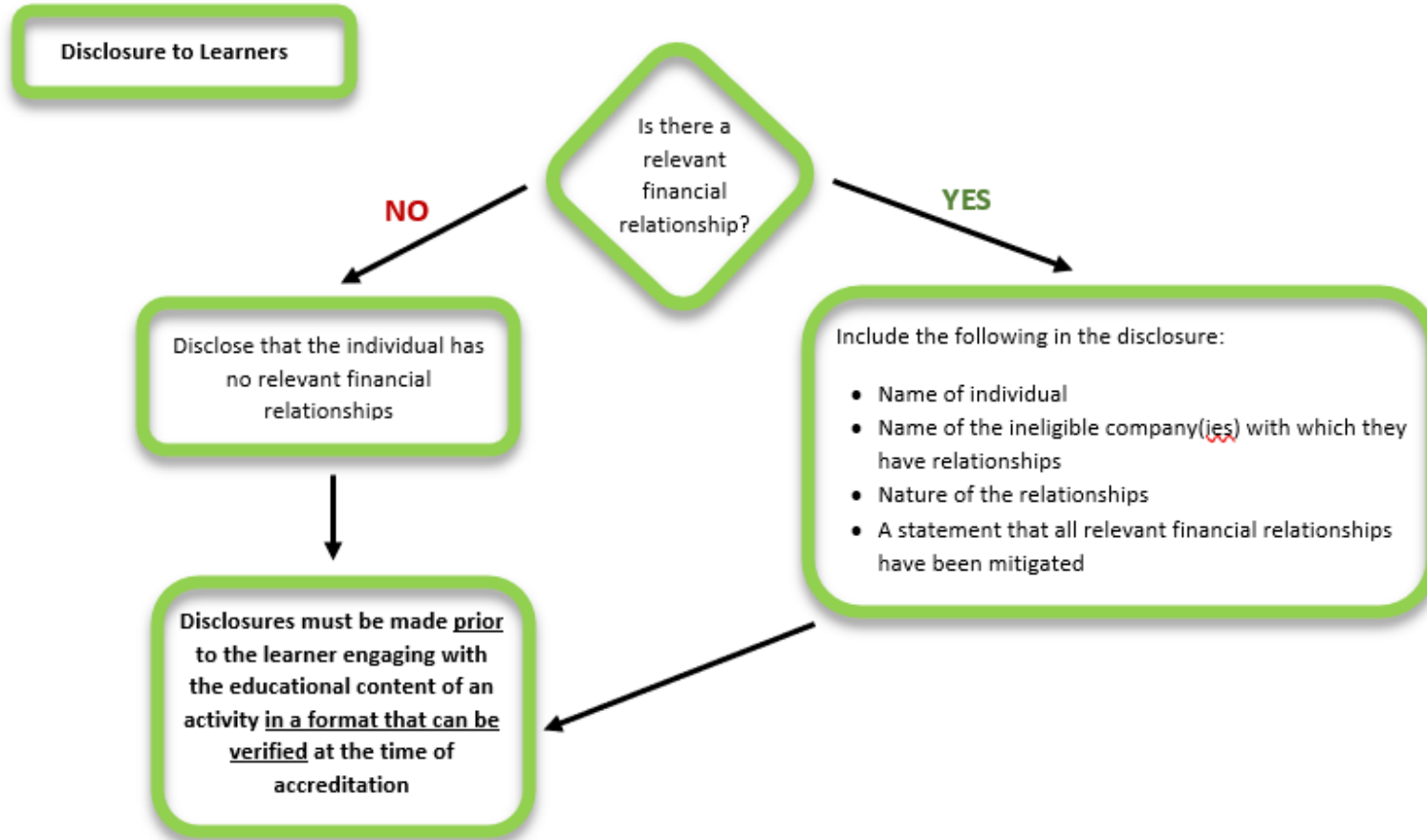


FLOWCHART FOR THE IDENTIFICATION, MITIGATION, AND DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

5. Disclosure to Learners

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Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education

The ACCME is pleased to provide this toolkit of resources to assist accredited providers in transitioning to the new Standards for Integrity and Independence. For this initial collection of tools, we have focused on Standard 1: Ensure Content is Valid and Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships. These two standards are applicable to all accredited providers. Use of these resources is completely **optional**. Many accredited providers have their own policies, procedures, forms, and mechanisms to facilitate the planning and delivery of accredited education—as you review your own practices, you may wish to check them against these resources to ensure you are positioned to meet expectations.

We look forward to working with the continuing education community to create and refine additional tools, as necessary. As always, we remain available for questions and assistance! Contact us at info@accme.org.



Key Steps

Overview of the 3-step process to identify, mitigate, and disclose relevant financial relationships.



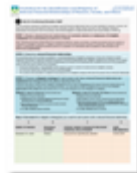
Sample Letter

Language you can use to explain to prospective planners and faculty why financial relationship information is collected.



Template

Compare your process or forms to this sample template to collect the right information about financial relationships.



Worksheet

Step-by-step process for identifying and mitigating relevant financial relationships.



Examples

Sample language that shows you how to communicate disclosure to learners.



Guidance

An example of how to enlist help from planners and faculty to ensure that clinical content is valid.



Template

An example of a tool to facilitate peer review to ensure that clinical content is valid.



Quick Tool

Use this sample tool to simplify educational planning when identification, mitigation, and disclosure are not required.

TOOLKIT FOR THE STANDARDS FOR INTEGRITY AND INDEPENDENCE

LET'S PRACTICE!

CASE #1 - AGENDA

What would you do?
Answer in the Poll

Leadership in a New Age

Your People

8:00 – 8:30 am

Your Organizational Culture Matters

8:30 – 9:00 am

The Paradox of Complex Communication

9:00 – 9:30 am

Discussion

9:30 – 9:45 am

BREAK

The Money

9:45 – 10:15 am

What to Know about Institutional Finances

10:15 – 10:45 am

Expanding Profits

10:45 – 11:15 am

Financing New Projects

11:15 – 12:00 pm

Small Group Discussion

12:00 pm

ADJOURN

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12:00 pm

ADJOURN

What would you do?

Answer: Nothing!

These are Non-Clinical Topics

**What would you do?
Answer on the Poll**

LET'S PRACTICE!

CASE #2 – PROPOSED AGENDA

Hepatitis B Virus: The Silent Epidemic: Prevention and Treatment Update

8:00 – 8:30 am	Welcome and Introductions – J. Kirk, MD, MPH
8:30 – 9:00 am	Developing Hepatitis B Vaccines from Trials to Full FDA Approval – J. Kirk, MD, MPH
9:00 – 9:30 am	Efficacy of Hepatitis B Vaccines – S. Spock, MSN, ACRN
9:30 – 9:45 am	BREAK
9:45 – 10:15 am	Results of the Tribble Trial: A Phase Study of Novel Trivalent HBV Vaccine – S. Spock, MSN, ACRN
10:15 – 10:45 am	Your Patient Has Hepatitis: What Now? – L. McCoy, DO
10:45 – 11:15 am	Pipeline of a New Hepatitis B Treatment – L. McCoy, DO
11:15 – 12:00 pm	The Future of the “Silent Epidemic” of HBV – J. Kirk, MD, MPH
12:00 pm	ADJOURN

LET'S PRACTICE!

CASE #2 – PROPOSED AGENDA

What would you do?
Answer: Collect Faculty
Disclosures

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**What would you do next?
Answer on the Poll**

FACULTY DISCLOSURES REVEALED...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceutical	Speaker's Bureau Stock Options	
Nyota Uhura	Activity Director	N/A	N/A	
Hikaru Sulu	Content Reviewer	N/A	N/A	
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	

FACULTY DISCLOSURES REVEALED...

What would you do next?
Answer: Determine if the companies listed are eligible or ineligible

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COMPANY RESEARCH REVEALED...

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Starfleet Pharmaceuticals – Produces Hepatitis B treatments

PhaserBiotech – Maker of Hepatitis B Vaccine and other vaccines

Riker Hospital – Provider of clinical services

Enterprise Pharmaceuticals – Has several promising Hepatitis B treatments in Phase 2 and 3 clinical trials

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

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Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals		

**Ask yourself:
Are these relevant
financial relationships
with ineligible
companies?**

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**Is mitigation necessary for Dr. Kirk?
Answer in the Poll**

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**How should we mitigate?
Make sure to address
each role**

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- Business Owner
- Employee
- Stocks (privately held ineligible companies)
- Equity Owner



Is at least one
of the
following
true?

- The content of the activity is not related to the business lines or products of their employer/company
- The content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations
- They are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

LET'S PRACTICE!

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9:00 – 9:30 am	Efficacy of Hepatitis B Vaccines – S. Spock, MSN, ACRN
9:30 – 9:45 am	BREAK
9:45 – 10:15 am	Results of the Tribble Trial: A Phase Study of Novel Trivalent HBV Vaccine – S. Spock, MSN, ACRN
10:15 – 10:45 am	Your Patient Has Hepatitis: What Now? – L. McCoy, DO
10:45 – 11:15 am	Pipeline of a New Hepatitis B Treatment – L. McCoy, DO
11:15 – 12:00 pm	The Future of the “Silent Epidemic” of HBV – J. Kirk, MD, MPH
12:00 pm	ADJOURN

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals	Speaker's Bureau Stock Options	
Nyota Uhura	Activity Director	N/A	N/A	
Hikaru Sulu	Content Reviewer	N/A	N/A	
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaco		

**What steps should be taken for Mr. Spock?
Answer in the poll**

Starfleet Pharmaceuticals – Produces Hepatitis B treatments

PhaserBiotech – Maker of Hepatitis B Vaccine and other vaccines

Riker Hospital – Provider of clinical services

Enterprise Pharmaceuticals – Has several promising Hepatitis B treatments in Phase 2 and 3 clinical trials

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals	Speaker's Bureau Stock Options	
Nyota Uhura	Activity Director	N/A	N/A	
Hikaru Sulu	Content Reviewer	N/A	N/A	
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmace		

**What steps should be taken for Mr. Spock?
Answer: He should be excluded**

Starfleet Pharmaceuticals – Produces Hepatitis B treatments

PhaserBiotech – Maker of Hepatitis B Vaccine and other vaccines

Riker Hospital – Provider of clinical services

Enterprise Pharmaceuticals – Has several promising Hepatitis B treatments in Phase 2 and 3 clinical trials

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals	Speaker's Bureau Stock Options	Activity Director Role: Decisions reviewed by non-conflicted planner Speaker: Review of content by H. Sulu
Nyota Uhura	Activity Director	N/A	N/A	
Hikaru Sulu	Content Reviewer	N/A	N/A	
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	Excluded
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	

DOCUMENTATION OF MITIGATION STEPS

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals	Speaker's Bureau Stock Options	Activity Director Role: Decisions reviewed by non-conflicted planner Speaker: Review of content by H. Sulu
Nyota Uhura	Activity Director	N/A	Will need to reassign content	
Hikaru Sulu	Content Reviewer	N/A		
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	Excluded
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals	Speaker's Bureau Special Consultant	
Nyota Uhura	Activity Director	N/A		
Hikaru Sulu	Content Reviewer	N/A		
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	

**What steps should be taken for Dr. McCoy?
Answer in the poll**

Starfleet Pharmaceuticals – Produces Hepatitis B treatments

PhaserBiotech – Maker of Hepatitis B Vaccine and other vaccines

Riker Hospital – Provider of clinical services

Enterprise Pharmaceuticals – Has several promising Hepatitis B treatments in Phase 2 and 3 clinical trials

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals		
Nyota Uhura	Activity Director	N/A		
Hikaru Sulu	Content Reviewer	N/A		
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech		
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	

**What steps should be taken for Dr. McCoy?
Answer: His content should be peer-reviewed for bias and content validity**

Starfleet Pharmaceuticals – Produces Hepatitis B treatments

PhaserBiotech – Maker of Hepatitis B Vaccine and other vaccines

Riker Hospital – Provider of clinical services

Enterprise Pharmaceuticals – Has several promising Hepatitis B treatments in Phase 2 and 3 clinical trials

LET'S FOCUS ON ONE INDIVIDUAL AT A TIME...

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals		<p>What steps should be taken for Dr. McCoy? Answer: His content should be peer-reviewed for bias and content validity</p>
Nyota Uhura	Activity Director	N/A		
Hikaru Sulu	Content Reviewer	N/A		
S'Chn T'Gai Spock, MSN, ACRN	Not an ineligible company			
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	

Starfleet Pharmaceuticals – Produces Hepatitis B treatments

PhaserBiotech – Maker of Hepatitis B Vaccine and other vaccines

Riker Hospital – Provider of clinical services

Enterprise Pharmaceuticals – Has several promising Hepatitis B treatments in Phase 2 and 3 clinical trials

DOCUMENTATION OF MITIGATION STEPS

Name of Individual	Individual's Role(s) in Activity	Name of Ineligible Company(ies)	Nature of Relationship(s)	Mitigation Steps
James T. Kirk, MD, MPH	Activity Director, Speaker	PhaserBiotech Starfleet Pharmaceuticals	Speaker's Bureau Stock Options	Activity Director Role: Decisions reviewed by non-conflicted planner Speaker: Review of content by H. Sulu
Nyota Uhura	Activity Director	N/A	N/A	
Hikaru Sulu	Content Reviewer	N/A	N/A	
S'Chn T'Gai Spock, MSN, ACRN	Speaker	PhaserBiotech	Employee	Excluded
Leonard H. McCoy, DO, MPH	Speaker	Riker Hospital Enterprise Pharmaceuticals	Employee Consultant	Review of content by H. Sulu

DISCLOSURE TO LEARNERS

Disclosures:

The following individuals have disclosed relevant financial relationships:

James T. Kirk, MD, MPH (Activity Director, Speaker)

Starfleet Pharmaceuticals – Speaker’s Bureau, Stock Options

Leonard H. McCoy, DO, MPH (Speaker)

Enterprise Pharmaceuticals – Consultant

All relevant financial relationships have been mitigated.

DISCLOSURE TO LEARNERS

Disclosures:

The following individuals have disclosed relevant financial relationships:

James T. Kirk, MD, MPH (Activity Director, Speaker)

Starfleet Pharmaceuticals – Speaker’s Bureau, Stock Options

Leonard H. McCoy, DO, MPH (Speaker)

Enterprise Pharmaceuticals – Consultant

All relevant financial relationships have been mitigated.

All other individuals in control of content have no relevant financial relationships to disclose.

DONE!

QUESTIONS?

REVISITING OBJECTIVES

- Understand how to determine if a financial relationship is relevant
 - Be able to select appropriate mitigation steps as necessary
 - Utilize proper disclosure statements
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