

COVID-19 Edition

Investigations: What Compliance Officers Need to Know

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AGENDA

1. Attorney Client and other Investigative Privileges
2. Investigation Planning, Strategy & Tips
- Your Checklist
3. Investigating in Collaboration with other Health Care Teams

Please note: opinions and suggestions of the presenter are not intended as legal advice and do not reflect the opinions of Sutter Health, or its affiliates.

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Poll Question

As a compliance investigator investigating during a Pandemic, I.....

- A. ... will be happy if I never see Zoom or Microsoft Teams again
- B. ... love the idea of video interviews – safer, less germs
- C. ... worry about effectively investigating now
- D. ... am ready to learn to do things differently

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I. Attorney Client & Other Privileges in Investigations

- Attorney Client Privilege
- Attorney Work Product Doctrine
- Waivers and Protecting Privileges
- Corporate Attorney-Client Privilege (Upjohn)
- Quality Assurance Privilege (Evidence Code §1157, federal law)

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Attorney Client Privilege

The Basics:

Attorney-Client Privilege requires:

1. Communication – oral or written
2. Made between a person who is a client and their counsel (a lawyer)
3. In confidence (should label and keep confidential)
4. For the purpose of seeking, obtaining, or providing legal advice

REMINDER: Client must be seeking legal advice (not just telling a secret to an attorney.)

Note: There is a CRIME FRAUD exception. Using an attorney client relationship to perpetrate or shield a crime eliminates the ability to assert this privilege.

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Poll Question

Attorney client privilege issues are applied and discussed in my organization:

- A. ... as needed and in accordance with our policies
- B. ... never
- C. ... only rarely in the VERY important cases
- D. ... only when our legal department pushes the issue

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Attorney Work Product Doctrine

Not as strong as attorney-client privilege but broader in scope.

Limited to preparations for litigation (or in anticipation of litigation)

Three elements required:

1. Documents and tangible things (such as an investigative report),
2. Prepared at the direction of counsel in anticipation of litigation or for trial, and
3. By or for a party or that party's representative.

REMINDER: Just because someone has a law degree (JD) after their name does not mean they can establish or assert these legal privileges.

Person must be serving the organization as legal counsel in order to initiate a privileged investigation.

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Privilege Waivers

Decided (or Intentional) Waiver

Sometimes the government requests a privilege waiver. Your legal counsel should carefully evaluate these requests!

Work Product Privilege may be waived if other party can demonstrate:

- Substantial Need and Undue Hardship
- Audit Related communications may not be privileged
- If you're not sure - talk to your attorney!

Inadvertent Waiver

When privileged information is inadvertently disclosed to someone who is not a party of the privileged relationship.

Don't let the cat out of the bag!

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Corporate Attorney Client Privilege

The attorney client privilege extends to corporations and organizations. This would apply to a compliance officer investigating on behalf of a health care entity when it is decided to investigate under privilege in order to provide legal counsel with the information necessary to give legal advice to the organization.

Elements:

- The communications were made by employees to corporate counsel who were providing legal advice to the corporation;
- The communications were made at the specific direction of corporate superiors;
- The communications concerned matters within the scope of the employees' corporate duties;
- The communications were made by the employees who were made sufficiently aware that they were being questioned by attorneys for the purpose of allowing the corporation to receive legal advice;
- And the communications were at all times treated as highly confidential when made and thereafter kept confidential by the company.

Upjohn v. United States, 449 U.S. 383, 394-95 (1981)

→ Consider Using Upjohn Warnings to establish these elements in high risk matters

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Privileged and Confidential Investigation Files

When an investigation is designated as privileged, investigative files should be labeled

“Confidential and Privileged”

- ✓ Internal access, including access to the portion of the file retained in your case management system, should be limited to authorized individuals.
- ✓ Additional access should be limited to authorized individuals solely on a need-to-know basis.
- ✓ Access to investigative files or materials by third parties should be approved by the attorney directing the investigation.

HOT TIP: If any investigative information is shared with a third party such as a regulator or law enforcement, an exact copy of what was shared, and all related communication should also be separately and carefully maintained in the investigative file. This should also be discussed and approved by counsel as this sharing may waive privilege for all.

All legal advice and/or attorney client communications shall be labeled and maintained as privileged and confidential.

HOT TIP: Don't do careless things that waive privilege. Be careful with “reply all” or posting on a “shared drive.”

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HOT TIP: Quality Assurance Related Privileges

If the issue being investigated also involves patient care with possible adverse patient impact, BE SURE to loop in your risk and quality partners.

There are separate, additional privileges in this venue with additional rules and requirements.

Example: A drug diversion case with false charting where patient does not get pain meds as prescribed and charted.

CDPH Reportable Adverse Events – 5 days

Cal. Health & Safety Code, Section 1279.1 (b) (6)

(6) Criminal events, including the following:

- (A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
- (B) The abduction of a patient of any age.
- (C) The sexual assault on a patient within or on the grounds of a health facility.
- (D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

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Why Bother With Privileges?

They help get the right facts to legal counsel so they can provide the right legal advice to the organization

They protect from legal discovery your conversations, or other interactions with counsel, designed to get the right information to help the organization make the right decisions

Typically you will not have to testify about your conversations with legal counsel

Given this, conversations with counsel should not be included in your investigative report

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Privilege Takeaways

DO:

- **DO:** email the attorney directly (use the "to" field not the "cc" field). Copy non-attorneys who need to stay informed.
- **DO:** be thoughtful when emailing both attorneys and non-attorneys. Consider separate emails or clearly separate legal and business questions.
- **DO:** state that you are seeking legal advice.
- **DO:** state when you are acting under the direction of counsel so that counsel can make a legal determination or provide legal advice.
- **DO:** understand that the corporation can waive the attorney-client privilege.
- **DO:** mark requests for legal advice or documents created under the direction of legal counsel for the purpose of counsel providing legal advice as A/C Priv.
- **DO:** be thoughtful in what you mark as privileged or A/C Priv.

DO NOT:

- **DO NOT:** widely circulate an attorney's email or copy multiple parties who do not need to know. Be thoughtful and analyze who should be included.
- **DO NOT:** disclose legal advice to third parties (e.g., "our attorney says . . ."). Instead just convey the company's position. This will help avoid inadvertently waiving privilege.
- **DO NOT:** feel you cannot copy attorneys on business/operations communications or ask attorneys for feedback on business/operational decisions, but understand privilege will not apply.
- **DO NOT:** forward an article or emails to a lawyer to "make" the forwarded information privileged.
- **DO NOT:** mark work privileged after the fact. There is no magic wand. These privileges must be initiated by an attorney or undertaken at the attorney's direction.
- **DO NOT:** fail to discuss requests from the government for privilege waivers with legal counsel

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II. Investigation Planning, Strategy & Tips

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Defining an Investigation

An investigation is a **fact-finding** endeavor. Investigations determine, to the best of the Investigator's ability and in good faith, what happened with respect to a particular incident – whether suspected conduct did or did not take place; what the circumstances were; who was involved; whether a violation of policy occurred.

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Poll Question

Prior to starting my investigation, I plan my investigation as follows:

- A. ... I spend some time planning and organizing, but keep options open for the investigation path to vary
- B. ... I prefer to wing it and let the case take me where it goes
- C. ... I spend at least one third of my time planning and organizing
- D. ... I use a handy checklist to prepare and organize my investigations

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SAMPLE CHECKLIST – CREATE ONE THAT SUITS YOUR ORGANIZATIONAL STRUCTURE AND POLICIES

DRAFT Compliance Investigations Checklist	
Check box when complete	
<p>Planning</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify issue and define scope, including: <ul style="list-style-type: none"> <input type="checkbox"/> Time period to be reviewed <input type="checkbox"/> Exact concern or question to be answered <input type="checkbox"/> Identify to whom the findings will be presented, suggest reviewer who: <ul style="list-style-type: none"> <input type="checkbox"/> Is independent from topic at issue <input type="checkbox"/> Has authority to take corrective action if needed <input type="checkbox"/> Decide whether the investigation will be conducted under the attorney-client privilege (Discuss with Counsel) <input type="checkbox"/> Identify person to lead the interview (consider each): <ul style="list-style-type: none"> <input type="checkbox"/> Leader has appropriate training and expertise <input type="checkbox"/> Leader has capacity and resources <input type="checkbox"/> Intake with person making complaint to clarify concerns (if compliant; based and if possible) <input type="checkbox"/> Set out deadline for significant stages of the investigation <input type="checkbox"/> Create separate file and mark confidential <input type="checkbox"/> Add initiation of the investigation to compliance log <p>Fact Gathering – Documents and Data</p> <ul style="list-style-type: none"> <input type="checkbox"/> Consider need for "litigation hold/preservation notice" <input type="checkbox"/> Obtain documents from internal sources (consider each): <ul style="list-style-type: none"> <input type="checkbox"/> Relevant individuals or departments <input type="checkbox"/> Documents in central files or storage <input type="checkbox"/> Email, shared drives or other electronic locations <input type="checkbox"/> Claims, reports, clinical documentation <input type="checkbox"/> Obtain external documents or data (e.g., EHR data, Medicare payment rates, vendor policies) or deem unnecessary <input type="checkbox"/> Consult internal experts or deem unnecessary <input type="checkbox"/> Consult outside experts or deem unnecessary <p>Fact Gathering – Witnesses and Experts</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify individuals with first-hand information (each "witness") <input type="checkbox"/> Consider order of witness interviews <input type="checkbox"/> Draft list of questions for each witness (with room to modify) <input type="checkbox"/> Interview witnesses <input type="checkbox"/> Summarize each interview in file <p>Identify law, standard, rule, or policies that apply</p> <ul style="list-style-type: none"> <input type="checkbox"/> Review company policies and procedures <input type="checkbox"/> Review applicable regulations or statutes <input type="checkbox"/> Review guidance from or regulations government agencies, <input type="checkbox"/> Determine whether legal or expert advice is necessary <input type="checkbox"/> Acknowledge ambiguity, if any: <ul style="list-style-type: none"> <input type="checkbox"/> Draft timeline or deem unnecessary <input type="checkbox"/> Identify undisputed or consistent facts <input type="checkbox"/> Identify and address conflicting testimony or data 	<p>Analyze Core Compliance Concerns</p> <ul style="list-style-type: none"> <input type="checkbox"/> Medicare/Medicaid overpayments (pick one): <ul style="list-style-type: none"> <input type="checkbox"/> None <input type="checkbox"/> Identify overpayments and refund <input type="checkbox"/> Duty to report to government agency (pick one): <ul style="list-style-type: none"> <input type="checkbox"/> No duty to report <input type="checkbox"/> Potential duty to report: Discuss with Legal Counsel <input type="checkbox"/> Other material regulatory or compliance risks (pick any that apply): <ul style="list-style-type: none"> <input type="checkbox"/> None <input type="checkbox"/> Significant legal, financial, or reputation risk to organization: Discuss with legal counsel and appropriate partners before initiating investigative activities <input type="checkbox"/> Conclusions indicate existence of larger compliance, cultural or operational issue <input type="checkbox"/> Deviation from standard of care or potential patient harm <p>Draft Report</p> <ul style="list-style-type: none"> <input type="checkbox"/> Prepare well written document, even if brief or only for the file, that includes (consider each): <ul style="list-style-type: none"> <input type="checkbox"/> Executive Summary <input type="checkbox"/> Compliance issue investigated <input type="checkbox"/> Efforts to gather and sources of information <input type="checkbox"/> Relevant standard, rule, or policy <input type="checkbox"/> Timeline or outline of key events <input type="checkbox"/> Factual and overall conclusions <input type="checkbox"/> Recommendations for remediation or other next steps <p>Identify Corrective Action</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify basis for non-compliance and most appropriate strategy for preventing similar non-compliance in the future <ul style="list-style-type: none"> <input type="checkbox"/> Update policies or deem unnecessary <input type="checkbox"/> Complete education and training or deem unnecessary <input type="checkbox"/> Take self-corrective action or deem unnecessary <input type="checkbox"/> Plan for future audit to ensure that corrective measures were effective or deem unnecessary <input type="checkbox"/> Document all corrective actions taken <p>Closure</p> <ul style="list-style-type: none"> <input type="checkbox"/> Present findings to appropriate party/committee <input type="checkbox"/> Compliance Officer closes the loop with: <ul style="list-style-type: none"> <input type="checkbox"/> Person who raised the issue <input type="checkbox"/> Significant witnesses <input type="checkbox"/> Senior leadership (as needed) <input type="checkbox"/> Organize and file documents <input type="checkbox"/> Update compliance log/system : investigation concluded

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"Good checklists...are precise. They are efficient, to the point and easy to use even in the most difficult situations. They do not try to spell out everything—a checklist cannot fly a plane. Instead they provide reminders of only the most critical and important steps—the ones that even the most highly skilled professional using them could miss. Good checklists are, above all, practical."
-- Atul Gawande

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Case Study – Investigation in the time of COVID-19

Strictly Hypothetical Compliance Complaint—Investigation Needed

Anonymous person called the hospital compliance line and reported an incident at NoName Community Hospital (NNCH). Caller reports that employee Sam Smith, an RN at NNCH has allegedly stolen 44 cases of N95 Masks, and other Personal Protective Equipment (PPE) from the back loading dock at the materials management area for the hospital.

Caller alleges that the incident occurred early in the morning on Saturday April 11, 2020. There is video surveillance in that area at all times. The caller reports that this should be investigated because the nurses and first responders for the hospital badly need the PPE. Caller also offers to provide photographs of the theft event while it was occurring but seeks to remain anonymous. According to Supply Chain each case of 1000 N95 masks is currently worth \$7,000 making (total value of alleged N95 mask theft is approximately \$308,000.)

Initial review of Sam's employment status with NNCH reveals that Sam had just returned from a seven month workers compensation related disability leave on April 9, 2020, and on April 16, 2020, Sam went out on a new disability leave. Alleged cause of new leave and origin of injuries is currently unconfirmed, but Sam alleges he has a back injury related to lifting heavy boxes while at work. Sam is also employed as a Labor Representative for the California Nurses Association (CNA)/ National Nurses United (NNU) and is frequently seen on social media out protesting PPE shortages at various Orange County hospitals.

On April 20, 2020, CNA represented nurses at NNCH file a Cal OSHA complaint alleging that NNCH is failing to provide them with adequate PPE as needed to properly care for patients.

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Identifying the Issues and Scope of the Investigation

Identifying the Issues and Determining the scope of an investigation before you start investigating can help you focus and move smartly along.

Specifically, formalizing the scope of an investigation assists the investigator in gathering the appropriate information from appropriate sources.

Sample Issues:

1. Did Sam Smith RN steal hospital property in violation of policy (or code of conduct) when he took the 44 cases of masks and other PPE from the loading dock?
2. Is Sam Smith RN committing disability fraud?

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Planning the Investigation

Identify Issues and Scope including:

- Time period at issue
- Exact concern or question(s) to be answered

Identify Stakeholder to whom the findings will be presented, reviewer should:

- Be independent
- Have the authority to take appropriate corrective action

Decide whether the investigation will be conducted pursuant to attorney client or work product privileges

- Discuss with counsel

Identify Lead Investigators and investigative partners , investigators should

- Be independent, and have appropriate training and expertise
- Have time and ability to get the job done within a reasonable period of time

Conduct intake with Complainant where possible to understand the full extent of the allegations

Draft preliminary timeline for investigative stages

Create separate file, mark confidential and add investigation into compliance log/system

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Conducting the Investigation

Witness Interviews

- Establish a standard opening statement (general subject of the investigation, role of the interviewee in the investigation)
- Is there anything that would prevent you from truthfully participating in the interview today?
- Anticipate likely questions from interviewee
- Be sensitive to the fact that being interviewed is generally stressful
- Try to listen more than you talk
- Ask open ended questions initially and funnel down to specific questions
- Develop a standard closing

COVID-19 Tips:

- Try to conduct the background interviews via video conference where possible. But before you try this in an actual investigation, practice with a colleague.
- Discuss in advance with the interviewee and seek to gain their confidence and comfort in your professionalism.

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COVID-19 Remote Interview SUGGESTIONS

If you are conducting remote interviews during COVID-19:

1. Practice with your interview venue or tool (Zoom, Microsoft Teams, etc.)
2. Discuss venue timing and process before the planned interview date/time
3. Expect technology glitches (face freeze, system failures, etc.)
4. Discuss recording rules that apply your organization and jurisdiction and whether recording will be allowed
5. Discuss whether others (besides the cat) may be in the room during your interview and how interruptions will be handled.
6. If you will be going over documents, discuss that in advance (another reason to try video interviewing)
7. Start with a positive, kind icebreaker.
8. Address privacy and confidentiality concerns

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Poll Question

Since the Pandemic started in March 2020, my experiences with witness interviews include

- A. ... using a video option (Teams, Zoom, Skype etc.)
- B. ... interviewing by phone
- C. ... interviewing in person
- D. ... using all of the above methods.
- E. ... none yet but I'm getting ready if needed

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COVID-19 Video Interview Considerations

These will help you convey trust and professionalism

Make sure your camera and lighting put you in the best light

- Try sitting back a bit from the screen
- Make sure your lighting is good
- Avoid distractions (plan for the best but expect the worst)
- Periodically summarize what you've learned from the witness
- Announce and formally include any partner or note taker
- Describe your actions while interviewing
 - Note taking, phone use (don't) dropped pen

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Drafting the Investigation Report

How should it be structured?

- Beginning
 - Summary of issue(s) being investigated
 - Executive Summary of investigation
- Middle
 - Factual summary
 - Scope of the investigation
 - Evidence considered
 - Analysis of evidence
- The End
 - Findings of fact
 - Conclusions
 - Exhibits

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Drafting the Investigation Report

How to assess credibility

- Consider the following factors
 - Inherent plausibility
 - Timeline of evidence
 - Corroborating evidence (is there video tape of the incident?)
 - Actual knowledge
 - Objective factors

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Drafting the Investigation Report

How to reach *defensible* conclusions

Understand the appropriate burden of proof

- Generally, the organization has the burden to make a good faith determination based on reasonable grounds that sufficient cause existed for its conclusion
- The organization does not need to prove with absolute certainty that the events occurred, but it needs to show it acted in good faith with reasonable certainty
- Reasonable certainty is measured by a **preponderance of the evidence** ... it was more likely than not to have occurred

Fifty Percent Plus a Feather

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Drafting the Investigation Report

Reach defensible conclusions based on facts and evidence

Types of conclusions

- **Substantiated:** The investigation revealed the evidence satisfies the burden of proof
- **Not Substantiated:** The investigation revealed the evidence did not satisfy the burden of proof
- **Inconclusive:** Unable to determine based on the available information (should be rare)

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Drafting the Investigation Report

Examples of conclusion phrases:

- “A preponderance of the evidence suggests that the allegation is true.”
- “There is no evidence to support the accused took the PPE, therefore allegation is not substantiated.”
- “A preponderance of the evidence supports the employee violated Policy No. [XXX] by taking the PPE off campus. Therefore, the allegation is substantiated.”
- “It was determined there is insufficient evidence to prove the employee misappropriated the PPE as alleged.”

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Drafting the Investigation Report

What makes a good investigative report?

1) **Clear**

- Clarity in language
- Clarity in overall coherence and logic
- A good executive summary

2) **Complete**

- Documents all aspects of the investigation
- Addresses all issues

3) **Concise**

- Succinct
- Straightforward to read

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Key Takeaways for the Investigative Report

- ✓ Begin your investigation with an outline and use your checklist throughout your investigation
- ✓ Frame the investigation and your report based on the scope and policies at issue
- ✓ Start writing your report with background, scope and issues early in the investigation
- ✓ Strive to document your factual, timely, and thorough investigation in a clear, complete and concise report
- ✓ Your investigation is only as good as the report you write and vice versa, your report is only as good as your investigation

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III. Investigating in Collaboration with Other Health Care Teams

Own swim lane?

Part of a team with a variety of risks at issue?

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Poll Question

When partnering with other investigative teams in my organization, I....

- A. ... prefer to stay in my swim lane unless I have no other choice
- B. ... stay alert for important crossover opportunities
- C. ... collaborate effectively with other teams
- D. ... worry that doing so will slow me down
- E. ... believe all of the above are true

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Partnering with Other Investigative Teams



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Example: Partnering with Other Investigative Teams

CDPH Reportable Adverse Events – 5 days

Cal. Health & Safety Code, Section 1279.1 (b) (6)

(6) Criminal events, including the following:

- (A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
- (B) The abduction of a patient of any age.
- (C) The sexual assault on a patient within or on the grounds of a health facility.
- (D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

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Get to Know Your Investigative Partners

Pot Luck

Ice Cream Social

Zoom Meeting

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Understanding Investigative Partner Perspectives

- Compliance/Privacy
- HR/Workers Compensation
- Labor Relations
- Physical Security
- IT Forensics
- SIU /Fraud Control

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Pulling it all Together

1. Apply Appropriate Investigative Privileges per your Organization's Standards
2. Plan, Strategize, Effectively Conduct, and Document your Compliance Investigations
3. Partner Effectively with other Organizational Investigators and Understand their Obligations and Risk Perspectives

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Questions?

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