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Report on Medicare Compliance Volume 30, Number 15. April 19, 2021 Two Checklists to Help Monitor Research Compliance

By Nina Youngstrom

Here are two checklists to help with oversight of research compliance (see story, p. 1).[1] They were developed by attorneys Andrea Lever and Genevieve deLemos of deLemos & Wever PLLC in Charlotte, North Carolina. The first checklist would be used in the context of an acquisition, when the acquiring entity is unaware that the acquired entity engages in research or management is unaware that research is taking place. "This could come up in physician practices where a physician may agree to participate in a study but not inform the practice manager about the study," Wever said. The second checklist is useful if an institution does research and wants to ensure it's "developing an adequate research compliance program to address the risks of the types of research in which it participates." Contact Wever at andrea@delemoswever.com and deLemos at genevieve@delemoswever.com.

Research Compliance Quick Check I: What to do when you suspect research is taking place at your institution

How to determine whether research is happening at your institution:

- Visual clues: study brochures, study kits, surveys/data collection, study binders, additional specimen collections, industry personnel on-site.
- Resource clues: request for additional staff, additional responsibilities for staff, study billing questions, training requests, institutional review board (IRB) inquiries.
- Administrative clues: payments from industry/contract research organization, monitoring visits, additional study-related patient visits.

What type of research is taking place?

- Outcomes, observational, interventional?
- Human or animal subjects?
- Phase 1, 2, 3 or 4?
- What is the funding source: unfunded, industry, private, state or federal?
- How many studies and what stage: enrolling, data collection, closed, etc.
- What are the current obligations of your institution and to what party?

Who is participating in the research?

- Identify principal investigator (PI), nurses, administrative staff involved in research.
- Are all employees of your institution?
- Have they all received required training: Collaborative Institutional Training Initiative and institutional?
- Are all participants listed on relevant study documents? FDA 1572 completed?

Locate and review study documents:

- IRB approval: what IRB approved and is it current?
- Contract/agreement between institution and funding body: obligations and timeline.
- Study budget, Medicare coverage analysis, protocol, consent forms, etc.
- Delegation logs, study binders, additional paperwork required by funding party.
- Financial conflicts of interest of PI disclosed to funding party and institution as required?
- Are research documents stored in a secure and organized manner?

Are human subjects adequately protected?

- Ensure IRB approval is current.
- Consent process and documentation completed by trained staff.
- Are vulnerable populations involved (children, elderly, pregnant women, etc.)?
- What information is being collected and shared with funding party?
- What financial obligations do enrolled patients assume?