September - Case Follow Up:

1. **Should Fox follow the advice of Badger to "get used" to Bear's behavior? Why/Why not?**

   Definitely not. Grabbing Fox's wrist and saying, "mind your own business" violates Baystate policy for Harassment in the Workplace (BH-HR-810), the institutions Code of Conduct for Workplace Behavior, and if federally funded, NIH's policy against inappropriate conduct (https://hr.nih.gov/workingnih/civil/harassment-and-discrimination), which includes "inappropriate touching or any form of physical intimidation or aggression." It may also constitute harassment if the action is based on Fox's sex, race or other protected classification status. Touching a person in a threatening manner without their consent may constitute an assault and should be reported to security.

   Additionally, Bear is demanding that Fox not report protocol deviations and noncompliance that could place human research participants and the Baystate Medical Center at risk. The IRB approved the protocol under the condition that BMI is not greater than 30 kg/m2. Enrolling patients with a BMI greater than 30 kg/m2 is a deviation that must be reported to the IRB. Also, since the deviation appears to be intentional, it may be considered serious or continuing non-compliance, which also must be reported to the IRB (HRPP Policy Manual Section 9 Protocol Exceptions and Deviations). In other words, Fox should report this protocol deviation to the IRB even if instructed not to do so by a superior. Any retaliation against Fox for reporting these deviations would be a violation of whistleblower protections.

2. **What are the potential consequences of not addressing the protocol deviation?**

   The Office of Human Research Protections (OHRP), which oversees human subjects research, may take some form of corrective action (such as a warning or determination letter) against Baystate for not reporting this deviation or not reporting it in a timely fashion. Deviations from well-designed inclusion/exclusion criteria risk compromising participant safety and/or data integrity.

3. **What resources are available to support Fox in navigating this situation?**

   Some resources include the: Baystate's HRPP/IRB Office, Sr. Director of Research Administration (Jennifer Sabbagh Peirce), Chief Research Compliance and Integrity Officer (Jennifer Pacheco), IRB Chair (Robert Baevsky, MD), Institutional Official of Research (Andrew Artenstein, MD), Dr. Bears' Department Chair, and Baystate Health Corporate Compliance Office. Fox should go to the HRPP/IRB first (and inform their immediate supervisor) because of concerns about study integrity and patient safety. The immediate supervisor could also be a good resource because and can work with the Research Compliance and Integrity Officer on this problem. Fox could (and probably should) also report the matter to the immediate supervisor because of Bear's inappropriate conduct. However, if Fox is not ready to take this step and want confidential advice, Fox should talk to the Corporate Compliance Office.

4. **What steps can be taken to ensure the safety and well-being of participants enrolled in the study and ensure the validity and reliability of the data collected?**

   Reporting the situation to the HRPP/IRB is the most important thing to do to protect the participants and data. The IRB will then decide what should be done once it receives the report. The IRB could suspend enrollment while it performs an investigation, withdraw patients from the study who were improperly enrolled, and inform affected participants about

what happened and what is being done about it. The IRB, in collaboration with the Sr. Director of Research and/or Research Institution Official, could place suspend Bear's research activities and require Bear to take additional training in human subjects protections. The Department Chair would also play a key role in this response and would work with the IRB.

5. **How might this case impact the trust and confidence of participants in clinical research at the Baystate?**

   It could have a negative impact on trust and confidence if the OHRP writes a determination letter to Baystate and the story is covered by the media. This bad publicity could make some participants more hesitant to enroll in research studies throughout the organization.

Additional Ethical Concepts Relevant to this Case

Protocol Deviation: Bear's enrollment of a participant with a BMI exceeding the specified limit constitutes a protocol deviation. Deviations from the approved protocol compromise the integrity and validity of the clinical trial.

Professional Judgment vs. Protocol Adherence: Bear's reliance on professional judgment as a justification for the protocol deviation raises concerns about the balance between individual discretion and adherence to established research guidelines. Ethical research requires strict adherence to approved protocols to ensure participant safety and data reliability.

Unwelcoming Work Environment: Bear's dismissive response to Fox's inquiry and anger create an unwelcoming work environment. A culture that discourages questioning compromises ethical oversight and may contribute to non-compliance and inferior research.

Physical Intimidation: Bear's physical aggression towards Fox by grabbing Fox's wrist is a clear breach of the Baystate's Code of Conduct and HR harassment policy and cannot be tolerated. Physical intimidation is unacceptable in any professional setting and violates the respect and safety of the staff.

Collaborative Decision-Making: A lack of collaborative decision-making and open communication within the research team is obvious. Ethical research requires a collaborative environment where concerns can be addressed with transparency and dissent is welcomed.

Professionalism and Accountability: Bear's unprofessional conduct and lack of accountability for protocol deviations undermine the principles of professionalism and responsibility in research.