This role play involves a principal investigator who is impatient to find significant results in an experiment involving animal subjects and a first year graduate student who is unsure how to respond to the PI’s suggestion to administer an intervention that is not in the protocol.

### Roles
- Principal Investigator (Dr. Miser)
- PhD Student (Cindy Lou)
- Colleague of the PI (Max)

### Scenarios
- Scenario One: Principal investigator tells PhD student to administer an intervention that is not in the protocol
- Scenario Two: PhD students asks for advice and

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### Role Play: PhD Student Role

**Character Description: Cindy Lou, PhD Student**

You are a first year graduate student working in the biology lab of Dr. Miser. You have been supervising an experiment that Miser designed to ascertain whether a certain anti-bacterial coating can lower the occurrence of infection linked to surgical pins. With Miser’s help, you have inserted pins into the left leg of twenty rabbits; ten of the pins are the industry standard pins, and ten have the anti-bacterial coating. You have also inoculated all of the rabbits at the insertion point with *staphylococcus aureus* bacteria and routinely administer morphine at 5 mg/kg to alleviate any discomfort the rabbits may be experiencing from the procedure. For six weeks, you care for the rabbits and monitor their progress, watching for any signs of distress or infection. No signs of distress or infection are observed at this time.

### Role Play: Principal Investigator

**Character Description: Dr. Miser, Principal Investigator**

You are working with a first year graduate student, Cindy Lou, on an experiment to determine whether a particular anti-bacterial coating can lower the occurrence of infection linked to surgical pins. The study design was based on an extensive literature review which seemed to strongly suggest the effectiveness of this particular anti-bacterial coating. If this intervention proves effective it will almost certainly lead to additional grant funding for successive projects. Your lab desperately needs to secure additional funding to remain afloat.
Role Play: Colleague of Dr. Miser

Character Description: Max, Colleague of Dr. Miser

You are an esteemed professor who has worked with Dr. Miser on multiple research projects over the years. You are known for your integrity and you are also known for being a dedicated friend. You are familiar with the anti-bacterial coating project that Dr. Miser and Cindy Lou are working on as you visit Dr. Miser’s lab a couple times a month to consult on several projects. You are the type of person that gets along with everyone you meet and as such you have developed a jovial relationship with Cindy Lou.

Scenario One

You have your monthly meeting with Dr. Miser to discuss the next step of the research project.

Prompt

Cindy Lou: “Hi, how are you?”

Miser: “Great, Thanks. How is the anti-bacterial project fairing? We have a lot riding on it.”

Cindy Lou: “Well, it’s been about 6-weeks and none of the rabbits seem to be particularly uncomfortable, and none of them show any signs of infection.”

Miser: “If we don’t get an infection, we won’t learn anything. It would be a shame to have put these rabbits through this, not to mention wasting all your time, without getting some results, I want you to help things along a bit. I want you to inoculate all of the rabbits with *Pseudomonas aeruginosa*. We’ll see what happens then.”

Cindy Lou: “The protocol specifies *Staphylococcus*, Dr. Miser”

Miser: “It’s only a small change. We’ve been approved to run the risk of infecting these rabbits; all we’re going to do is give the process a little boost.”

Cindy Lou: How do you respond?

Questions to Consider

1. Is Dr. Miser wrong to not submit an IRB modification to the study protocol to inoculate the rabbits with a pathogen that was not originally in the protocol?
2. What ethical guidelines is Dr. Miser violating if he goes forward without first receiving IRB approval for the protocol modification?

Scenario Two

Prompt

Cindy Lou: “Hi Max. Do you have a couple of minutes? I have something that I’d like to discuss with you.”

Max: “Why so serious? And of course, I can spare 15 minutes.”

Cindy Lou: “It’s a serious matter. Let’s take a walk outside the building if that’s okay with you?”

Max: “Absolutely.”
*They leave the building and begin their walk*

_Cindy Lou:_ “You know Dr. Miser well and I know you also take research ethics very serious which is why I think you’re the perfect person to talk to regarding this. Dr. Miser and I have run into a serious obstacle in our anti-bacterial coating project in that the rabbits are failing to become infected with _staphylococcus aureus_. When brainstorming how to move forward with the project, Dr. Miser asserted that we should inoculate the rabbits with _pseudomonas aeruginosa_ and maintained that we do not need to submit a modification to the IRB to approve this change. Our current protocol doesn’t support this new procedure at all. I’m beginning to think that I will have to contact our department chair or perhaps the IRB if Dr. Miser can’t see reason soon.”

_Max:_ “So you would throw your own PI under the bus because of a small kerfuffle such as this? I expected better from you, Cindy Lou. It’s times like these that PIs need the support of their lab members the most! A less understanding man would bring this to Dr. Miser straight away and in a blink of an eye your career in academia would be over like that! But I’m a fair, kind man so I tell you what. Promise never to bring this nonsense up again and I’ll promise to keep this between us. What do we say?”

_Cindy Lou:_ How do you respond?

**Questions to Consider**

1. Where did Cindy Lou go wrong?
2. Who would be an appropriate person for Cindy Lou to voice her concerns to?

**Take Away Points**

- Changes to procedures used in protocols that are already approved MUST be reviewed by your IACUC prior to implementation.
- When considering who to consult regarding the responsible conduct of research, make sure you consult someone who is trusted and reliable.

**References**