



Guidance for Community Representatives

- Do not be shy about asking for information to be repeated or more clearly and plainly stated. Part of the responsibility of the IBC is to present information needed to make a judgment about safety practices and containment that is appropriate. The basis for these decisions can be explained without requiring PhD-level training in molecular biology.
- Don't get lost in the science. Most Community Representatives do not have extensive training or experience to challenge scientists on technical grounds and they should not feel the need to. It's more important to look for signs of a strong "biosafety culture":
 - A thoughtful planning process overall (training, documentation, PPE, signage)
 - Attention to detail in describing the work, training, and safety measures taken
 - Conscientious consideration of actual (previous) or potential safety issues
 - Openness and vigorous discussion at the IBC (i.e., Is anyone on the IBC pushing back or asking detailed questions other than you?)
 - Are they taking safety seriously?
- Give the IBC Chair or biosafety contact person feedback on the meetings. What works and what doesn't work? What do you need from the IBC Chair that you're not getting? Are you getting material ahead of time to review, if that helps you prepare?
- When you ask a question about some aspect of the safety program, even if it goes beyond the requirements of the NIH Guidelines, there should be a thoughtful and knowledgeable response. Some valuable "non-science" questions include:

Protocol Questions

- How will the experiment(s) be conducted?
- If previously approved, what has been learned about the protocol since it was approved? Have any changes been made?
- "Walk me through the procedure." Ask for a step-by-step description of the lab protocol that is under consideration.

Safety Questions

- Are glass sharps used? If so, are there enhanced practices required or training offered?
- Is centrifugation (or any aerosol-generating process) being used?
- What personal protective equipment (PPE) is being used for this work?
- What containment level (BSL) is used at each phase of the work and why?
- Are Biosafety Cabinets (BSCs) to be used for any part of this work? Why?
- Any special precautions being taken with the waste stream? Autoclave before removal? Any biological waste not being treated by an outside vendor?
- Is there a system for logging spills, "near spills," and other incidents that may produce an exposure to a potentially infectious or harmful agent?
- Is there an Emergency Response Plan in place (Fire/Evacuation/Explosion/Spill)?
- Are there contingency plans for other emergency scenarios (esp. loss of power)?
- How long can the biological materials be maintained with power loss?

Lab Administration & Documentation Questions

- o How is biological material from outside sources being tracked or screened or strain-verified? Is there documentation from the vendor or clinical source? If clinically sourced, is there any sample screening for pathogens?
- o Is any of this material to be shipped or moved from where it was received? If so, how will it be tracked and contained?
- o Are there standard operating procedures (SOPs) describing any of these processes? Can I review them?
- o Who is responsible for lab SOPs and who reviews them? **Note:** SOPs are not necessary for every procedure in the lab, but should be worked out for riskier and more critical tasks or procedures.

Staff & Training Questions

- o Who is conducting the work described in the protocol? Are they represented at the IBC (not to vote, but to address questions and provide detail)?
- o How are they trained and who supervises their work and safety training?
- o Is the staff growing? Is there a lot of turnover of bench staff (scientists)? Why?
- o Who provides Occupational Health services? Have they met with staff? Have any staff visited because of a work-related incident? Any 911 or hospitalization events?

Best Practices for Working with Community Reps

- Send technical information (project summaries and protocols or SOPs) to membership with enough time for clarification and simplification. Consider explanatory material, a short glossary of terms, or any other clarifying info.
- If a community member requests a simpler or more complete explanation of any aspect of a protocol or the biology behind the protocol, please make the time to review it with them. Unnecessary jargon and parenthetical definitions can demystify these documents.
- Include a review of questions raised in the previous IBC meeting as a review and a means of avoiding redundancy. These may also serve as a helpful guide to IBC members and can provide continuity between meetings.
- Keep the agenda focused on the biological risk assessment and other safety topics. These are the primary responsibilities of the IBC. Other biological safety considerations:
 - o PPE requirements
 - o Training
 - o Administrative practices
 - o Incident reporting (spills, exposures, and near-misses) from the past year
 - o Non-rDNA biological work
 - o Emergency planning and preparedness

These and other safety-related topics should also be part of the agenda. If there are no new protocols to approve or review, these other biosafety topics can fill out the agenda.

- Seek feedback from the community member about the level of detail and selection of topics for the meeting. Their responses and observations can help improve the discussion and direct the host company/institution to improve its level of participation.

Last reviewed: June 5, 2023