

Common Issues Causing Delays in IBC Approvals

1. Investigators can save time by reviewing protocols written by staff or trainees. A 10-minute review by the investigator *prior to the "Submit" action*, will catch issues that delay acceptance and reduces the time spent on corrections required by the IBC.
2. Researchers should take time to ensure that biosafety containment levels are consistent throughout the application, and that recombinant agents are duly identified within the specific agent sections of the application.
3. Researchers that are attempting to add personnel and cannot find the individuals in the drop-down menus should ask the personnel if they have completed the required training. *For more information see the [IBC Quick Training Videos](#), particularly sessions 3, 5 and 8.*
4. List all genes and inhibitory RNAs to be expressed including all oncogenes and tumor suppressors.
Working with vectors overexpressing oncogenes and down-regulating tumor suppressors requires BSL-2+ precautions.
5. For CRISPR/Cas use, state whether guide RNAs and Cas protein are expressed from the same vector.
Expression of guide RNAs and either Cas, Talen or ZFN proteins from the same Lentivirus vector increases biocontainment levels to BSL-2+.
6. Use of three and four plasmid strategies to construct HIV-1 based viral vectors may allow production and use of the Lentiviral vectors at BSL-2 levels.
See also note 2, above.
7. For production of Lentiviral vector stocks in the lab, provide all details requested by the IBC to expedite the review. If obtaining stocks from a vendor, identify the source/vendor.
8. Requests for AAV downgrades require documentation of the viral purification procedure and purity data when obtaining the AAV stocks from vendors not specifically indicated on the [IBC AAV Guidance document](#), or from individual collaborators inside or outside of UPitt/UPMC. *All AVV is to be used under BSL-2 unless the protocol specifically requests the downgrade, even when vectors are from known Vendors.*
9. When providing the Project Summary information, detail separate sections (Aims) of the project that summarize the experimental design and procedures versus providing lengthy passages describing the strategies for biosafety or cut/paste from a grant application.
10. Limit the details of project justification details copied from grant proposals. Extraneous material not relevant to biosafety pasted in from other documents can be disruptive to reviewers and can delay reviews.

11. Do NOT include materials or agents that are not going to be used but are for a vague “future” or “possible” use. Only include agents that will be used in the described research.
Amendments can be made at any time to update the application to accommodate new agents.
12. A list of useful resources and helpful links can be found on the [IBC website](#). Find the [IBC Guidance Resources](#) under the “[Guidance and Forms](#)” pull down menu on the IBC website (www.ibc.pitt.edu).
13. Question 10 (*Basic Information Section*) on the application should only be completed if there is an individual to support the administrative burden for the research laboratory.
Note that if the individual is to have read/edit capabilities on the protocol application, they must also be listed in the Research Personnel section.
14. Question 3 in the Risk Group Section of the application should only be completed if the study is a clinical trial for Human Gene Transfer research.
Question 2 should be left blank for clinical research trials.