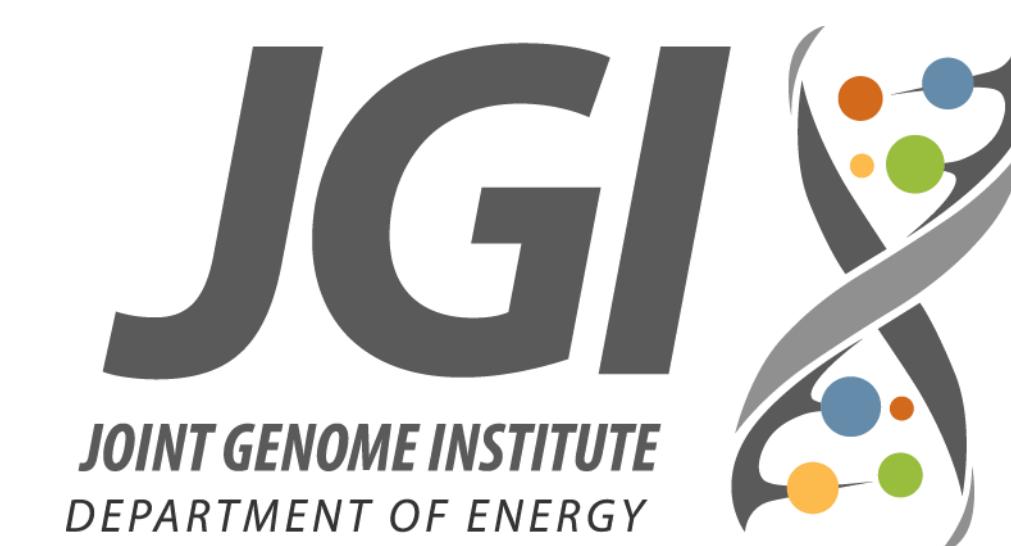


# The Joint Genome Institute's Synthetic Biology Internal Review Process

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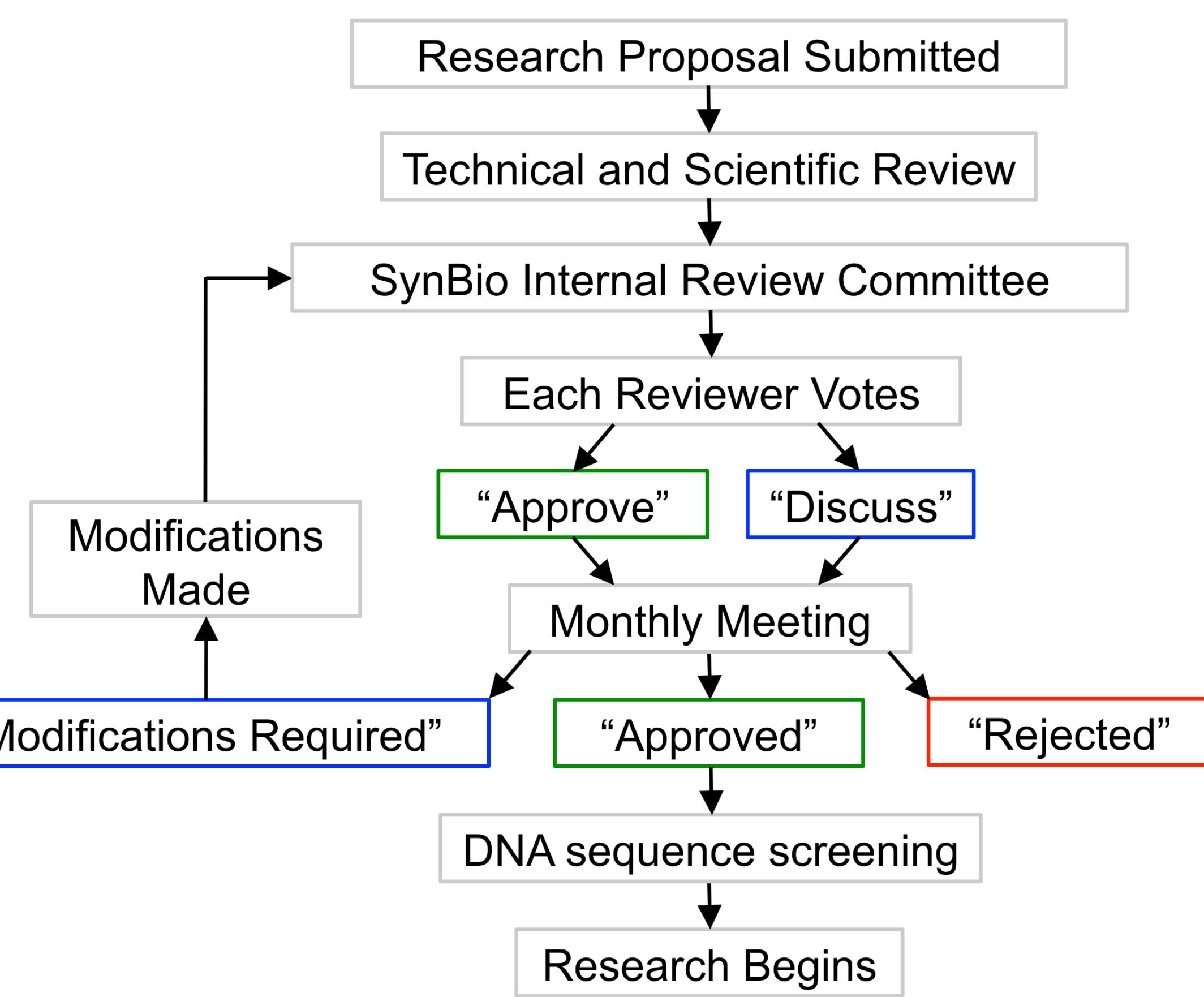
## INTRODUCTION

Synthetic biology has the potential to accelerate science and bolster economic growth. However, like any new technology, synthetic biology could be misappropriated or result in unintended consequences. Serious concerns have been raised over the possible intentional use of synthetic biology approaches to engineer pathogenic organisms as well as the possible accidental environmental release of genetically engineered organisms. Scientists pursuing synthetic biology research must diligently consider issues such as these.

The U.S. Department of Energy (DOE) Joint Genome Institute's (JGI) Synthetic Biology Internal Review process seeks to assess, beyond technical and scientific merit, certain broader aspects (e.g., environmental, biocontainment, biosafety, or biosecurity) of the research proposals associated with the JGI's DNA synthesis program. The purpose of this internal review process is two-fold: 1) to assess the broader aspects of the research, request proposal modifications if issues of concern are not sufficiently addressed in the proposal, reject research proposals where issues of concern are not or can not be satisfactorily addressed, and output a paper-trail audit of the review process; and 2) to encourage and educate researchers to more extensively consider the broader aspects of their research, including beyond the immediate research itself.

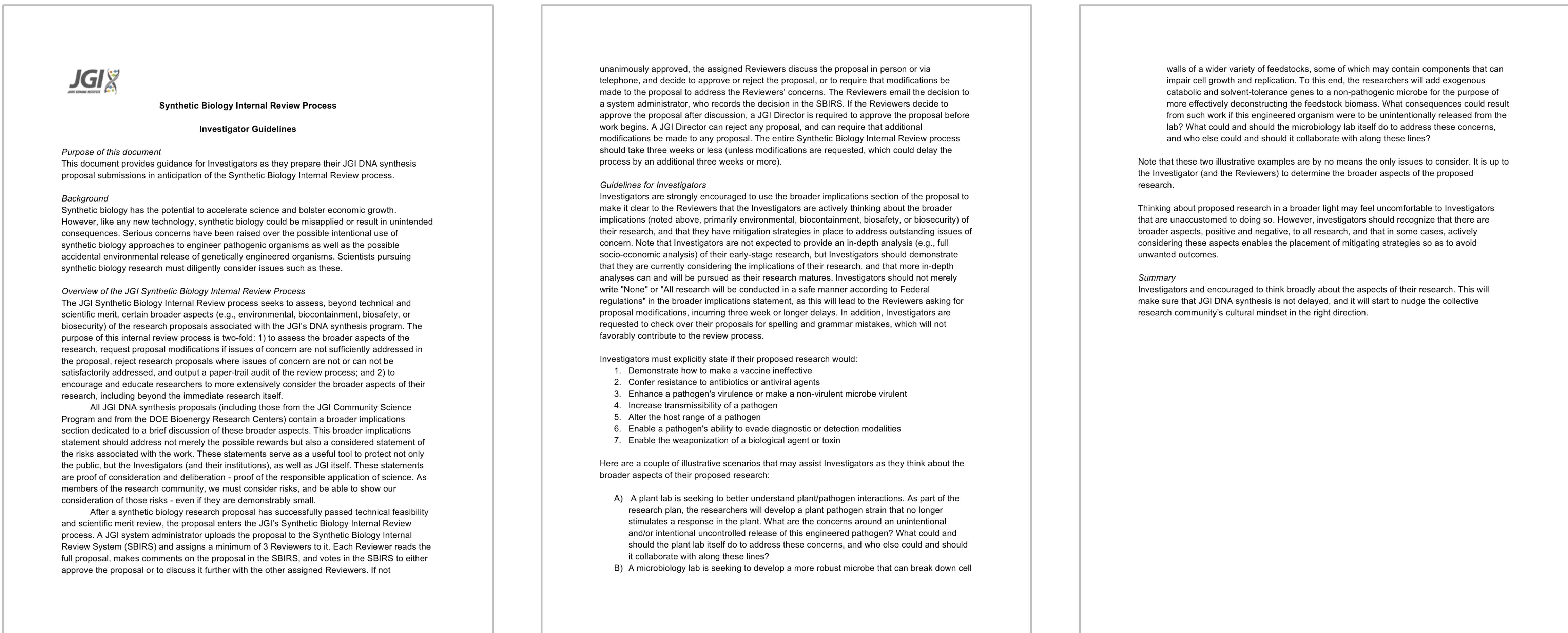
All JGI DNA synthesis proposals (including those from the JGI Community Science Program and from the DOE Bioenergy Research Centers) contain a section dedicated to a brief discussion of these broader aspects. This "broader implications" statement should not merely address the possible rewards, but also a considered statement of the risks associated with the work. These statements serve as a useful tool to protect not only the public, but the Investigators (and their institutions), as well as JGI itself. These statements are proof of consideration and deliberation – proof of the responsible application of science. As members of the research community, we must consider risks, and be able to show due diligence of our consideration of those risks - even if they are demonstrably small.

## PROCESS OVERVIEW



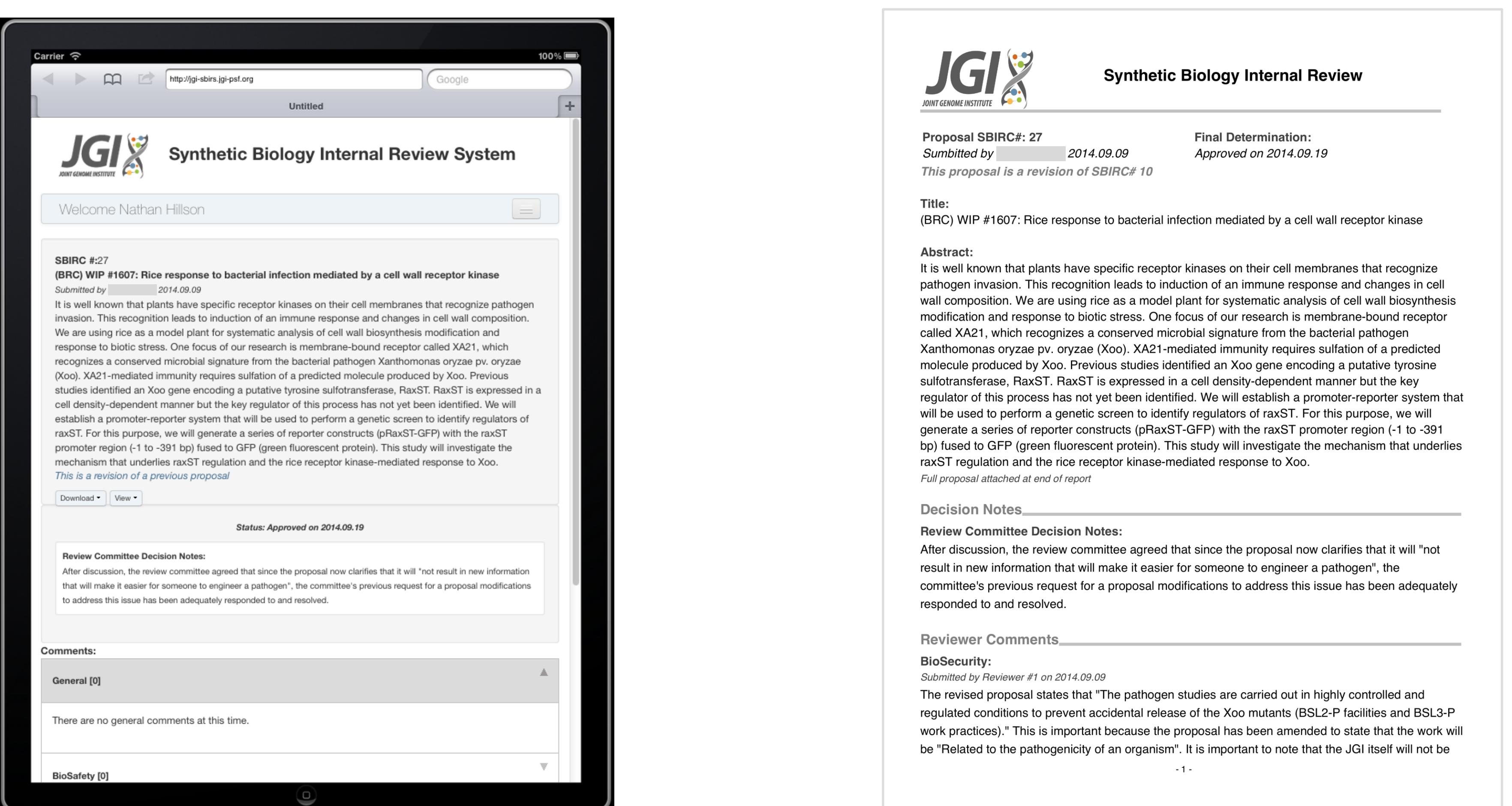
## GUIDANCE for INVESTIGATORS, REVIEWERS, and DIRECTORS

It is crucial to the review process to provide clear guidance to the investigators preparing proposals, reviewers assessing the proposals, and institutional directors signing off on the approval process, to explain the purpose of the Synthetic Biology Internal Review Process and to set consistent expectations.

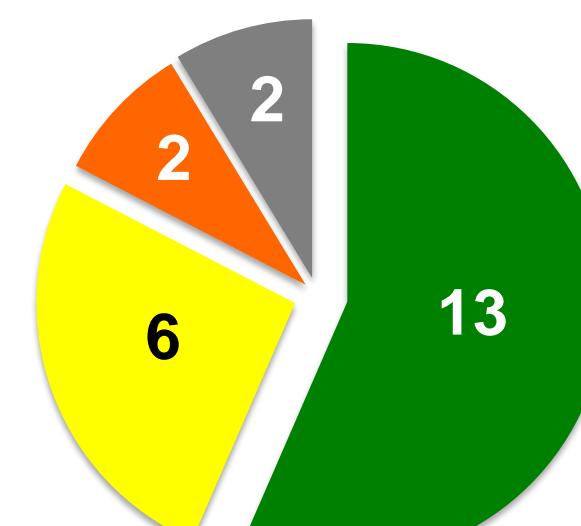
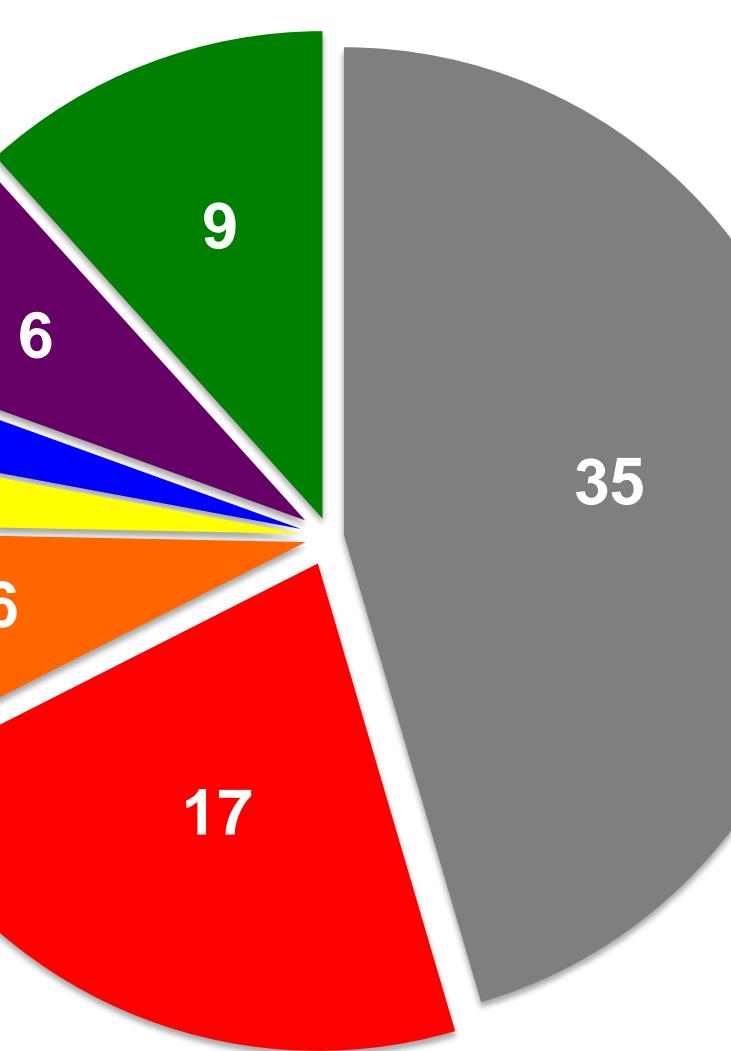
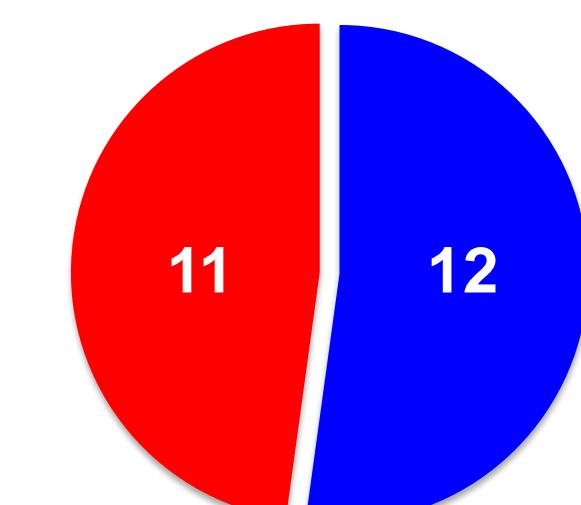
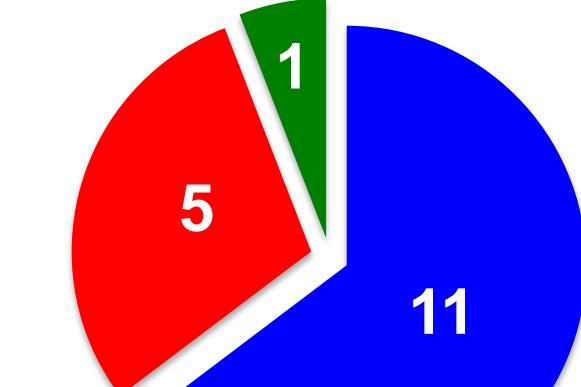


## WEB-BASED REVIEW SOFTWARE and REVIEW PROCESS PAPER TRAIL

Web-based review software (accessible by Reviewers on mobile devices; left) facilitates the review process, and will enable other institutions to more easily stand-up their own review processes. Paper-trail audit documentation (right), automatically generated at the conclusion of each review, increases process transparency and provides a historical record noting the issues of concern and proposed mitigation strategies associated with each research proposal.



## REVIEW PROCESS STATS TO DATE



## NEXT STEPS

Aside from continually improving the internal review process, next steps include expanding the pool of Reviewers, preparing a manuscript that describes the review process and results to date, as well as placing the freely open-source review software in a public software source code repository (e.g., GitHub).

## ACKNOWLEDGEMENTS

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