AUTHENTICIATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

Dr. Rowe and his laboratory are dedicated to conducting research of the utmost rigor and transparency, and this Research Program will authenticate key biological and/or chemical resources through a broad range of approaches at a frequency that is appropriate for each line of inquiry. Because there are no Specific Aims on this proposal, we do not provide details on authentication of specific resources, which may vary over the period of this grant award as justified by findings. To assist the reviewer in assessing our activities in this regard that we expect to conduct with R35 support, we have provided some general examples below. As protocols are conducted, communication with the NIH will be conducted.

1) The Rowe laboratory has internal standards to ensure the validity of biological and chemical resources. For example, we implemented a quality control system to maintain the uniformity and health of cells grown in our cell culture program. Furthermore, all cell lines are periodically tested for the absence of mycoplasma contamination. In case of contamination or accidental loss of materials, a central repository of cell stocks with limited access is maintained. We also have standard operating procedures that ensure consistency in the reagents that are generated and disseminated to the field. Clinical grade research assays all operate with Standard Operating Procedures that are maintained and updated annually.

2) Regular maintenance is performed on all equipment not only for efficient work flow, but also for reproducible results on tests using biological and/or chemical resources.

3) To authenticate findings, it is a standard of the Rowe laboratory to include positive and negative controls in all studies, to run multiple tests for each assay, and to perform numerous complementary assays. For example, it is customary that we validate data on CFTR function with data on CFTR expression as assessed by assays including HRP (cell surface expression), western blot, and mRNA quantification.

4) Standard Rowe laboratory procedures include a bi-annual inventory check to ensure that all biological and chemical resources are current, stable, and will elicit rigorous data. All laboratory personnel are instructed to report immediately any observation in materials that may indicate the slightest compromise in quality and/or efficacy.

5) Authentication data from all materials received from external vendors will be reviewed and additional tests conducted, as deemed necessary. These activities also will extend to materials generated within our own laboratory.

6) Publication of research results in peer-reviewed journals is expected of all members of the Rowe laboratory, providing an additional level of authentication. Facilitating this, all personnel have access to training and assistance offered by UAB's Lister Hill Library in subjects related to publication and data reporting. In addition, we maintain a strong presence at multiple regional, national, and international conferences. In particular, we emphasize early data presentation at the NACFC and ATS conferences.

7) Animal models including novel CF rats characterized at UAB; cell models including primary human airway epithelial cells from CF and non-CF donors; resources including micro-OCT, small animal bronchoscopy and exposure system, Flexivent, micro-CT; techniques and methodologies including nasal potential difference measurement, patch clamp analysis, single channel analysis, detection of spontaneous cough in ferret, measurements of mucociliary clearance by Tc99 inhalation; and associated reagents are openly shared through the Rowe laboratory with investigators at both UAB and other institutions. This ensures research transparency as well as supports the development of the most relevant, authenticated experimental designs using cutting-edge methods.