## DATA MANAGEMENT AND SHARING

Consistent with the goals of the SBIR/STTR program goals and as stipulated in the SBIR/STTR Program Policy Directive, effective May 2, 2019, we may withhold all data from sharing for 20 years after the award date. Here we present our plan for scientific data management, preservation, and archiving.

**Element 1: Data Type**

**A. Types and amount of scientific data expected to be generated in the project:**
This project will generate data related to developing a first-in-class drug for IPF against a highly novel target, prostaglandin F2 alpha (PGF2$\alpha$) receptor (FP), as described in detail in the Research Strategy. Data types will include measurements of body weight, histopathology, collagen and hydroxyproline levels, cytology and cytokine levels, mortality rate, lung function, fibrillar collagen deposition, collagen gene expression, transcriptomics, pharmacokinetics, and toxicology. All such data generated at Maipl Therapeutics will be analyzed in Excel files or equivalent. Histopathology will include image analysis of prepared slides. Open access (e.g., ImageJ) or commercially available image viewing software will be used for image-related tasks where relevant as well a direct viewing under microscope. All scientific data, including raw and analyzed data, will be stored in a secure cloud-based platform to allow instant access to all investigators in the grant.

**B. Scientific data that will be preserved and shared, and the rationale for doing so:**

All scientific data will be preserved securely in the cloud. Based on the SBIR/STTR Program Policy Directive, all data may be withheld from sharing for 20 years after the award date.

**C. Metadata, other relevant data, and associated documentation:**

In addition to the scientific data listed in A, study protocol and/or plans will also be preserved locally and in the cloud.

**Element 2: Related Tools, Software and/or Code:**

No specialized tools are needed for accessing the generated data with the exception of image viewing and analysis software (e.g., imageJ or commercially available software package). All user documentation will be archived locally and version controlled. The statistical analyses described in the application will be done using a commercially available statistical analysis package.

**Element 3: Standards:**

**A. Data standards for clinical protocols –Common Data Elements (CDEs)**

Common Data Elements (CDEs) are not specifically planned.

**B. Data standards for all plans:**

Maipl Therapeutics will apply common data standards to the scientific data and associated metadata generated in this proposal and made accessible to the research team. We do not anticipate using any open data repositories. Data will be stored in common and open formats in secure cloud-based storage platforms that can be accessed by the research team. Information about research protocols and analysis processes will be recorded and maintained using lab notebooks (manual and/or electronic), which will be accessible to the research team and shared alongside our data.

**Element 4: Data Preservation, Access, and Associated Timelines**

**A. Repository where scientific data and metadata will be archived:**

All scientific data will be preserved in the cloud. Based on the SBIR/STTR Program Policy Directive, all data may be withheld from sharing for 20 years after the award date.

We will make the results and accomplishments of this research available to the research community and to the public at large by the timely release and sharing of data as we choose. As a means of sharing knowledge, the investigators supported by this grant may seek to publish the original research in primary scientific journals. Each publication that results from the grant-supported research will include an acknowledgment of NIH grant support and follow guidelines regarding free access to published materials. Information on each publication resulting from work performed under the NIH grant-supported project will be included in the annual and/or final progress report submitted to the NIH awarding office.

We will work with other investigators to respond to requests for data for reanalysis or assistance replicating the research, and all reasonable requests will be accommodated, given a sound scientific rationale and purpose, appropriate data and privacy protections, feasibility of complying with the request, and compliance with the policies of all participating institutions and organizations. Maipl Therapeutics is also open to collaboration with outside groups who express interest in this approach.

The investigators will assert copyright in scientific and technical articles based on data produced under the grant where necessary, but we will also make every effort to keep technologies developed as a result of this research project widely available and accessible to the research community. If additional patents are filed and the technology licensed, we will only seek exclusivity in cases where this approach is determined to be the best route for successful development of the technology for public use and benefit.

**B. How scientific data will be findable and identifiable:**

All scientific data will be preserved by cloud storage. Based on the SBIR/STTR Program Policy Directive, all data may be withheld from sharing for 20 years after the award date.

**C. When and how long the scientific data will be made available:**

All scientific data will be preserved by cloud storage. Based on the SBIR/STTR Program Policy Directive, all data may be withheld from sharing for 20 years after the award date.

**Element 5: Access, Distribution, or Reuse Considerations**

**A. Factors affecting subsequent access, distribution, or reuse of scientific data:**

Maipl Therapeutics agrees to identify where the data will be available and how to access the data in any publications and presentations we decide to share and distribute; we will acknowledge the funding source in any publications and presentations arising from this research project.

**B. Whether access to scientific data will be controlled:**

See response to Element 4.

**C. Protections for privacy, rights, and confidentiality of human research participants:**

See response to Element 4

**Element 6: Oversight of Data Management and Sharing**

Compliance with this plan will be monitored and managed by the PI of this proposal.