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University of Rochester

University of Rochester TraCe-bMPS: Advancing reproducible FDA-facing research with protocols.io

The University of Rochester's Translational Center for Barrier Microphysiological Systems (TraCe-bMPS) develops microphysiological systems (MPS), or tissue-chip models, as human-relevant alternatives to animal testing in drug development.

As the center moves toward regulatory readiness and expands collaborations across academic, industry, and external testing sites, ensuring reproducibility and consistent documentation is critical. To support these goals, TraCe-bMPS adopted protocols.io as a centralized platform for SOP development, version control, and collaborative protocol management.

The challenge

Novel Approach Methodologies (NAMs) require rigorous documentation to demonstrate reproducibility across laboratories and support regulatory acceptance.

TraCe-bMPS needed to:

- Standardize experimental procedures across teams and institutions
- Capture critical laboratory knowledge in documented workflows
- Manage SOP updates while maintaining controlled versions
- Support quality systems and regulatory expectations
- Enable reproducibility across external testing sites

The solution

Beginning in Spring 2024, TraCe-bMPS implemented protocols.io as the foundation of its SOP governance framework.

Researchers and quality personnel could review, refine, approve, and version protocols while maintaining a complete audit trail.

Using the platform, the team documented laboratory procedures, assays, equipment workflows, and quality-system processes in a structured, collaborative environment.

The platform also helped transform informal laboratory practices into standardized procedures that could be shared and reproduced across institutions.

> *"The goal is reproducibility, very good control, in very specific contexts of use."*
>
> **James McGrath, PhD, Director, TraCe-bMPS**

> *"We chose protocols.io specifically so SOP development could be done in a structured and reproducible manner."*
>
> **Joan Adamo, PhD, Director, Office of Regulatory Support, in the Clinical and Translational Science Institute**

Results

TraCe-bMPS established a scalable documentation framework that supports standardized SOPs, version control, cross-site collaboration, reproducibility, training and onboarding and regulatory readiness.

Following iterative protocol refinement, the center successfully demonstrated reproducibility both internally over the course of several months and at external testing sites using a collection of shared procedures.

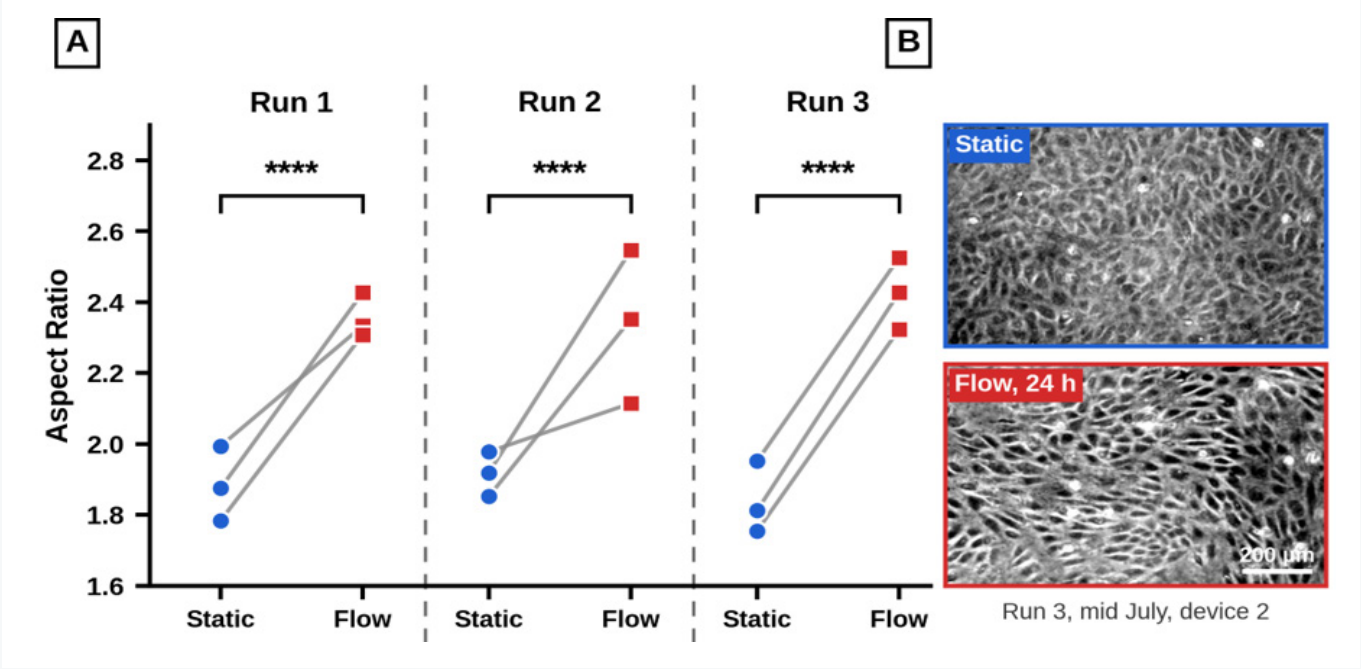


Figure caption: Follow the same protocol, get the same answer. The experiment was run three separate times, in June, early July and mid July 2025, starting fresh each time with new cells and three new devices. Every experiment was executed following the SOP detailed on protocols.io. In each device, cells were grown for 24 hours either in still culture or under steady flow, then measured. (A) Under flow the cells stretched out, by about a quarter on average, and the difference was statistically significant in every one of the three runs. (B) The same result down the microscope: still culture above, 24 hours of flow below, where the cells have elongated and lined up together. Scale bar 200 µm.

> *"This is really a central point for regulatory submissions."*
>
> **Joan Adamo, PhD, Director, Office of Regulatory Support, in the Clinical and Translational Science Institute**

Looking ahead

As NAMs, such as tissue-chip technologies, continue to emerge and develop, TraCe-bMPS views reproducible, shareable protocols as essential scientific infrastructure.

By implementing structured SOP governance through protocols.io, the center has strengthened collaboration, supported quality-system development, and created a foundation for scalable, reproducible research.

Build a foundation for reproducible science

Scan to discover how **protocols.io** helps research teams build confidence in reproducibility across laboratories, collaborators, and regulatory submissions.

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