

THE NORTH AMERICAN 3Rs COLLABORATIVE

Participation in a New NA3RsC Workstream or Discussion Group

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| 1. Workstream/Working Group Title | Microphysiological Systems (MPS) <u>Hub</u> |
| 2. Name of group chair or co-chairs, if known | John Lowman and Ben Cappiello |
| 3. NA3RsC Sponsor (if any) | <u>Szczepan Baran</u> |
| 4. Is this a strictly NA3RsC topic, or should other groups be invited? | <u>IQ Consortium, NCATS, NC3Rs</u> |
| 5. Relevant background: Why is this work needed? Has any other group addressed it? Relevant publications, guidances? | <p>MPS have the potential to become an integral part of the drug development workflow. Animal studies are often not predictive of human clinical results, <u>in vivo animal models provide valuable information to better understand human and animal diseases and to develop new medicines, devices and treatment modalities for disease. While the value of animal models in advancing science and medicine is well established, the scientific community is continually working to identify novel approaches that may lead to improved clinical translation and relevance of animal models. Furthermore, the scientific community is committed to the 3Rs (replacement, reduction, and refinement), which are rapidly evolving as a part of advancing optimal science and animal welfare.</u></p> <p><u>Emerging technologies and MPS provide the potential for clinically-relevant assays and opportunities to screen in a non-animal alternative system</u> during preclinical discovery and development. Such alternatives will enable crucial opportunities to reduce, replace, and refine animal testing.</p> <p>Other groups <u>Manuscripts from IQ, https://www.ncbi.nlm.nih.gov/pubmed/28622731</u></p> |
| 6. Scope, focus, objectives of the group | <p><u>The MPS Hub will include all commercially-available MPS (cell providers, cell culture platform providers, and in vitro CROs) being used in drug discovery and development. We will welcome peripheral members, but the core group will focus on models already translated into use. The goal to increase the</u></p> |

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Note: This scoping document is in draft form, with review comments included. Once the Working Group (WG) is formed, the WG will work together to finalize the document.

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| <p>7. Target deliverables</p> | <p>interaction and adoption of <u>MPS technologies, including 3D cell culture assays, spheroids, organoids, tissue-chips, and organs-on-chips.</u></p> | <p>Deleted: these</p> <p>Deleted: , not to just create new academic ideas for new models.</p> <p>Deleted: Models included will include</p> <p>Deleted: Create a plan for THE</p> |
| <p>8. Type of expertise sought</p> | <ol style="list-style-type: none"> 1) <u>Manage creation of a centralized annual meeting on MPS and submit the application to NCATS.</u> https://grants.nih.gov/grants/guide/notice-files/NOT-TR-20-005.html 2) <u>Grow the online expo where in vitro alternative developers and technologies are showcased and turn it into a lead up to, and continuation of, the meeting.</u> 3) <u>Facilitate collaboration for session proposals and posters highlighting impact in the MPS space for scientific conferences at meetings (i.e. SOT, ACT).</u> | <p>Deleted: I</p> <p>Deleted: V</p> <p>Deleted: A</p> <p>Deleted: s</p> <p>Commented [BNA5]: I think this needs reworked. What is the actual goal here? To facilitate ongoing collaboration and communication around areas for opportunity and refinement in the MPS space?</p> <p>Deleted: Submit</p> <p>Deleted: for session</p> <p>Deleted: at</p> <p>Deleted: and/or</p> |
| <p>9. Any restrictions on the number or role of nominees</p> <p style="color: white; font-size: small;">If the size of the group is to be limited, enumerate the objective criteria that will be used for final selection.</p> | <ul style="list-style-type: none"> • <u>Scientists and stakeholders interested in using MPS technology for any purpose. This can include basic research, drug discovery and development and internal/regulatory decision makers.</u> • <u>Technology providers interested in collaboration with scientists and stakeholders to facilitate new development and faster adoption of technology into the research market.</u> <p>30 technology providers and 30 end-users</p> | <p>Deleted: Pharma, MPS service providers, MPS product providers, CRO's, academics using established MPS technologies</p> |
| <p>10. Anticipated length of the project</p> | <p><u>12 months – 5 years</u></p> | <p>Deleted: Application due August 2020.</p> |
| <p>11. Anticipated time commitment for members</p> | <p><u>Initially, members are anticipated to commit approximately 1 hour per month to teleconferences with end-users and quarterly teleconferences with technology providers. The frequency/duration of meetings will be revisited once membership is established.</u></p> | |

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| <p>12. What is needed for involvement? E.g.</p> <p style="padding-left: 20px;">Name and contact information CV or bio Statement of interest</p> <p>13. Deadline for submitting nominations for involvement</p> <p>14. Any other relevant information or requests</p> | <p><u>Outside of these scheduled meetings, members are expected to dedicate approximately 4-10 hours of work annually to this working group in some capacity (e.g., additional engagement, creating/reviewing deliverables, etc.).</u></p> <p>- <u>Name and contact information</u></p> <p>- <u>CV, bio, or company descriptor</u></p> <p>- <u>Statement of interest</u></p> <p><u>March 25, 2020</u></p> <p>https://grants.nih.gov/grants/guide/notice-files/NOT-TR-20-005.html</p> |
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