

Dear Colleagues,

Last week, we wrote you to address the important work that Northwestern researchers are pursuing to respond to the COVID-19 pandemic. Among many other advances, our investigators have [identified novel drug targets](#) for disrupting viral proteins, [launched a clinical trial](#) to test an anti-viral drug, received an NSF RAPID grant to produce innovative [self-sanitizing masks](#), and have been developing [3D printing methods](#) to manufacture critical supplies for the hospitals. We encouraged our researchers to pursue this important research, but we did note that any items produced for patient use in our hospitals — whether therapeutics, diagnostics, PPE, or devices — could not proceed without our approval.

Since that communication, we have continued working closely with our hospital colleagues and FDA compliance attorneys to better understand the regulatory requirements for use of these items, and specifically for those items expected to be in short supply, including face shields, swabs, respirator masks, and more (a useful summary can be found [here](#)). The FDA regulates these products to ensure quality, safety, and efficacy of these designs, including when they are manufactured without proper quality controls and processes. In response to the COVID-19 outbreak, the Agency has taken steps to expand the availability of these medical devices. These include issuing [Emergency Use Authorizations](#) and enforcement policy guidance that provides more flexibility in manufacturing and distributing devices having new designs, materials, and manufacturing methods. *Even so, FDA is mindful of safety during this time, and is still imposing certain minimum requirements on these new products and producers. Depending on the product, these include notices, registrations, formal approvals, or ongoing reporting obligations.*

**In light of these facts, our updated guidance is as follows:**

- You are encouraged to continue pursuing your research. This includes developing new designs, materials, and manufacturing methods, as well as developing prototypes and testing these designs — and with approvals from the IACUC or IRB as necessary. You also may engage collaborators and advisers. But no items produced in the University can be directed to, or used in, patients without approval by the undersigned.
- In parallel, we ask that you continue to notify your Associate Dean for Research and the VPR about any ongoing design, prototyping, fabrication, or production projects in response to COVID-19.
- Research aimed at mitigating the COVID-19 pandemic is considered “essential” research; be sure to request authorization for your lab personnel working on these projects by notifying your Associate Dean for Research, as explained [previously](#). Ensure that all on-campus research abides by social distancing and good hygiene practices.
- Understand that the successful translation of research advances to patient care will most commonly rely on an outside partner with experience in FDA-approved products. If your work is on a path to benefit patients, we suggest you identify a commercial or

suitable non-for-profit. You are invited to contact Jim Bray, the Director of [Corporate Engagement](#), and Alicia Loffler, the Executive Director of [INVO](#), for guidance in engaging partners. Of course, INVO will prioritize COVID-19 projects for arranging licenses with your partner.

- We remind you to check our [website](#) for future updates to this guidance.

We also are thankful that many of you have shared examples of how our peers are mobilizing their research activities for patient care. While most of these examples are still at an early stage, or have relied on an outside partner, we remain interested in understanding other examples for translation. Please do share with us those instances where you have been able to confirm that University-produced items are being used with patients.

We recognize that some of you are frustrated by the regulatory requirements that must be addressed before your work can bring benefit to patients and medical care providers. We also recognize that government regulations and exemptions may change if the pandemic accelerates and we will update our guidance as appropriate.

We are proud of the many ways Northwestern research has mobilized to address challenges brought to us by the pandemic, and we will continue working with Global Marketing and Communications to share our successes with the broader community. As always, we invite you to contact us and your Deans with your questions and suggestions.

Thank you for your extraordinary commitment during this challenging time.

**Milan Mrksich**

Interim Vice President for Research

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