

In response to the University's State of Emergency and requests to engage in research related to COVID-19, the Wexner Medical Center (WMC), College of Medicine (CoM), and Comprehensive Cancer Center (CCC) have developed this **COVID-19 Basic, Translational, and Clinical Research Policy** to guide requests to engage in COVID-related research.

COVID-19 is an infectious disease and research involving it necessitates additional precautions. To ensure that research moves forward carefully and the impact of that research on personnel and resources is carefully considered, COM/CCC/WMC has agreed to the following framework.

### **Human Subjects**

Studies will be categorized into four classes.

- **Class I:** Studies as part of due process of care: Studies in this class use specimens that are collected in the normal conduct of care. No additional data and/or specimens will be collected.
- **Class II:** Studies that propose to collect participant data or biobank research specimens without clinical intervention: Studies in this class allow for the collection of biospecimens and surveys. No clinical intervention allowed.
- **Class III:** Studies that provide new interventions based on phenotype: Studies in this class may involve interventions as part of other studies (e.g., studies to test the effect of a drug on patients who are positive for COVID-19). There are no control patients. Additional data and/or specimens may be collected.
- **Class IV:** Studies that include control patients: Studies in this class may involve interventions as part of other studies (e.g., studies to test the effect of a drug on patients who are positive for COVID-19). Control subjects are allowed. Additional data and/or specimens may be collected.

### **Overarching Framework for Data Collection**

The PARTNERship for Enhancing Research (PARTNER) – is a method for engaging patients in research that has many advantages for researchers. By linking studies through a common framework, we can ensure that data collected for COVID-19 studies are made available to the community of scholars engaged in similar research. PARTNER mimics the Total Cancer Care protocol, however it is for use in the general hospital population. Note: Investigators who contribute specimens through PARTNER will retain control of those specimens. Please visit the COVID Research [FAQ](#) for more detailed information.

### **Approval for COVID-19 Research**

**Research PIs will be required to complete an impact and planning assessment** for any type of COVID-19 research that involves staff being on site in any of the research or medical facilities (including wet-lab research only) and for any research involving face-to-face interactions. Research requests will be submitted via [REDCap](#). For human subject research, approval will be required prior to submitting for IRB approval of a new study or a modification of an existing study. The College will review all research requests and will respond within one business day.

Requests will be assessed based on:

- ❖ Scientific merit
- ❖ Safety of the healthcare team
- ❖ Safety of the research team
- ❖ Potential negative impact on the clinical mission
- ❖ Impact on Personal Protective Equipment (PPE)
- ❖ Resourcing
- ❖ Impact on associated staff and infrastructure
- ❖ Appropriate regulatory / biosafety plan (following CDC processes and IBC approval)
- ❖ Additional information based on specific study