Phased Return for Penn Medicine Clinical Research

This document describes PSOM’s phased scaling back up for clinical research. It assumes that all faculty and staff will adhere to all Penn Medicine, University, City and State ‘Shelter at Home’ directives and ‘return to work’ requirements as they are released, inclusive of testing, use of PPE, temperature checks, and provision of strategies, such as shift work, to ensure continued social distancing practices within the workplace. These requirements will be described in detail in a separate document that will be released by the University and PSOM. It can be expected that this document may change over time, as requirements change. We will communicate these changes to you as they occur.

As PSOM actively plans for a scaling back up we encourage Clinical Research PIs to actively anticipate, discuss and address their staff’s concerns and anxieties about returning to work, transportation challenges and child/eldercare responsibilities and proactively plan for how they will be responsive to them within their respective research teams, Divisions and Departments. The timing of the first phase will be determined by the University in partnership with PSOM. At this time, we do not anticipate the first phase occurring prior to June 4th, 2020. The duration of time between each phase is not known at this time and it will be determined by the University in partnership with PSOM and will be driven by State and City directives.

Return to full clinical research activity will occur in a phased manner that necessitates a categorization and continued prioritization of PSOM’s clinical research portfolio. This document describes the categories of clinical research that may resume during each phase of scaling back up. Departments are asked to work with their Clinical Research Faculty to prepare for the phased return by reviewing their current Clinical Research portfolio and generating a summary of which projects fall into which phase of the return using the categories described below. Please email summaries of Non Oncology Clinical Research to Emma Meagher, MD and Oncology summaries to Bob Vonderheide.

Existing prioritization committee structures will remain in place throughout the phased process. It is anticipated that review by the committee will only be required when there is uncertainty in the characterization of a project or when there is a desire by the department or a faculty member to begin a project that has been categorized into a later phase of the return plan. An escalation process will be available in situations where consensus has not been reached or approval to proceed has not been granted and the faculty member or department chair wishes to appeal the decision.

Four categories are outlined below.

**Category A:** Research activity that can continue as of May 8, 2020. Please note that during this period the University’s ‘Shelter at Home’ requirements remain in place.

1. **Essential Clinical Trials** include the following
   a. New and existing clinical trials that hold the clear prospect of benefit for patients with life threatening or serious conditions
   b. In-person study visits required to assess safety of patients who were enrolled in clinical trials prior to the pandemic
c. New and existing clinical trials where enrollment into the trial is the only available option for the patient

2. COVID Clinical Research

3. **NEW!** As clinical services lines begin the “resurgence” to clinical practice, new and existing clinical trials and non-interventional clinical research where the research activities that must occur on site can occur during inpatient stays and during patients’ already scheduled clinical visits and those same research activities can be executed without requiring that clinical research support staff return to campus and the PI has confirmed that imaging, IDS, CHPS, CVPF and all other research specific services are available to execute the trial.

4. Research that can be conducted remotely should continue to be conducted remotely with all staff working remotely. This includes:
   a. Trials where in person visits can be eliminated or conducted remotely via telemedicine and investigational meds can be delivered to the participants’ home
   b. Non-interventional research where research participants do not need to come on campus, research staff can effectively execute the research activities remotely and direct contact with participants is not required.

**Caveats:** PIs and CRCs conducting ‘Essential Clinical Trials’ and ‘COVID Research’ work (# 1 and 2 above) are considered essential employees and are required to work on-site and adhere to all requirements to reduce likelihood of infection of staff and research participants. Research staff involved in # 3 above, and monitoring, auditing, training, SIVs, research systems support, financial management, contracting, and regulatory support activities are not permitted to return to campus at this time. Clinical research participants are not permitted on campus unless they are a participant in an approved essential trial, a COVID research study or they are on campus for clinical care reasons as in-patients or outpatients.

**Category B.** Describes additional clinical research that will be permitted to recommence, and associated staff will that be permitted to return on-site during the *first* phase of re-entry. We do not anticipate this happening prior to June 4th, 2020.

1. Investigator initiated existing and new First in Human clinical trials of Penn developed products.
2. Existing investigator-initiated NIH or other ‘not for profit’ funded research that do not meet the criteria defined in category A.
3. Existing investigator-initiated industry-funded research that do not meet the criteria defined in category A.
4. Research that can be conducted remotely should continue to be conducted remotely with all staff working remotely. This includes:
   a. Trials where in-person visits can be eliminated or conducted remotely via telemedicine and investigational meds can be delivered to the participant’s home.
   b. Non-interventional research where research participants do not need to come on campus, research staff can effectively execute the research activities remotely and direct contact with participants is not required.
**Caveats:** Clinical research staff involved in direct contact with research participants enrolled in the research described in 1-3 above will be required to be on site (PIs and CRCs). Research staff involved in #4 above and in training, SIVs, research systems support, financial management, contracting, and regulatory support will continue to work remotely. Penn monitors and auditors would be permitted on site only to review documentation that is not accessible remotely. Industry and CRO monitors will be permitted on site if they meet all standards required for Penn employees.

**Category C.** Describes additional clinical research that will be permitted to recommence, and associated staff will that be permitted to return on-site during the **second** phase of re-entry. We do not know when phase 2 will begin.

1. New investigator-initiated NIH or other ‘not for profit’ funded research.
2. New investigator-initiated industry-funded trials.
3. New and existing industry-sponsored clinical trials.
4. Research that can be conducted remotely should continue to be conducted remotely during the second phase of re-entry. This includes:
   a. Trials where in person visits can be eliminated or conducted remotely via telemedicine and investigational meds can delivered to the participant’s home.
   b. Non interventional research where research participants do not need to come on campus, research staff can effectively execute the research activities remotely and direct contact with participants is not required.

**Caveats:** Staff involved in direct patient contact would be required to be on site (PIs and CRCs). Research staff involved in #4 and in the following activities would continue to work remotely: training, SIVs, research systems support, financial management, contracting, and regulatory support. Penn monitors and auditors would be permitted on site to review documentation that is not accessible remotely. Industry and CRO on-site monitoring, auditing and SIVs will be permitted on-site if they meet all standards required for Penn employees.

**Category D.** Describes additional clinical research that will be permitted to recommence during the **third** phase of re-entry.

1. Everything else that has been conducted remotely during the pandemic and there is a wish to return to campus
   a. Chart reviews
   b. Data collection
   c. Observational studies
   d. Journal clubs/ lab meetings
   e. In-person/on-site trainings

**Caveats:** At this stage, all clinical research support staff required for optimal execution of clinical trial work would be required to be on-site. A new normal of staff working full- or part-time remotely would be considered appropriate for PIs, CRCs, and staff who support the execution of research with no required in-person patient, staff, or system interactions.