CONSULTING GROUP

Research Ethics and Compliance
Management Solutions

Tel: 347.862.9321
Fax: 347.862.9323

www.thehrpconsultinggroup.com

THINK ABOUT…

The Safe Resumption of Research Activities When COVID-19 Restrictions are Eased or Lifted

INTRODUCTION:
With the current COVID-19 pandemic, institutions, researchers and IRBs are confronted with ethical and operational challenges well-beyond those that most have ever faced. HRP Consulting provides information such as this "Think About" to help organizations, researchers, and IRBs develop appropriate solutions to these challenges. There is no one best practice in circumstances such as this. It is our hope that this information helps you identify and develop the solution that will work best for your organization and research community. A few tips:

- Remember to document your decisions and the thought process behind them, these records will be important as we all move forward
- Remember to check federal, state, and local orders (e.g. shelter-in-place), and any organizational or facility restrictions or requirements, to ensure that your solutions are workable and comply with these rules
- Remember to reassess often – information is evolving so quickly and what made good sense today may change tomorrow (e.g., because of a new or modified federal or state order, because of new guidance, because of emerging evidence, etc.)
- Remember to flag protocol records that may require follow-up action down the road

SUMMARY:
Institutions have taken a wide variety of actions to manage research during this COVID-19 pandemic. Some institutions halted research all together, some only allowed research that did not involve in-person activities to continue, others allowed some essential in-person research to continue, and others left the decision-making to investigators. Likewise, there was been wide variation in the management of changes made to research to mitigate the risk of COVID-19, in the processing of new studies unrelated to COVID-19, and in the management of continuing reviews.

As restrictions are eased or lifted in some regions, HRP wants to remind you of some considerations as you begin to think about moving your research program forward within the 'new normal' environment.

First and foremost, is the need for investigators and IRBs to appreciate that the parameters for what constitutes 'normal', have now changed. As institutions consider re-starting paused research or resuming in-person research activities, institutions, investigators and IRBs will need to consider the fact that the risk of COVID-19 infection will still be present and that modifications may be needed to minimize the risks associated with the research. Investigators and IRBs should anticipate the need to re-evaluate research protocols and develop plans to manage this. Studies with in-person procedures that were originally considered minimal risk (e.g., interviews, focus groups, blood draws, etc.) may need re-consideration as greater than minimal risk, due to the risk of COVID-19 infection. The risk-benefit analysis for a protocol may have shifted. The adequacy of provisions to minimize risk, to monitor safety, and to protect privacy and confidentiality may need to be re-evaluated. It may no longer be feasible to resume certain research as originally proposed and approved due to facility shut-downs, supply shortages, furloughs, etc.

Consider:

- Whenever possible, that studies that were modified to virtual/phone/remote formats continue to conduct those procedures as modified
- Studies being submitted to the IRB for initial approval should include virtual/phone/remote formats for as many procedures as possible

Tel: 347.862.9321
Fax: 347.862.9323
www.thehrpconsultinggroup.com

- For paused studies, whether it is possible to modify some or all face-to-face procedures to virtual/phone/remote formats prior to re-starting the study
- The security of virtual platforms (e.g., Zoom, Skype)
- Changes to data management (e.g., for remote access and use) and the security of these procedures
- Whether research activities could be added to a routine care interaction instead of involving a separate visit
- Whether PPE (e.g., masks, face shields, gowns, gloves) is needed, and whether it is available for purposes other than clinical care
- Whether screening procedures for COVID-19 need to be added to the protocol, or whether they are required by the institution or facility where research activities will occur
- Whether changes need to be made to safety monitoring plans
- Whether consent forms and other materials need to be modified to address the risk of COVID-19 or to incorporate changes made to research activities
- Whether furloughs impact the ability to safely conduct the research
- Handwashing protocols
- Frequent disinfecting of all surfaces potentially touched by subjects and the research team. The institution's department for Environmental Health and Safety should provide to researchers an acceptable protocol to meet standards for proper disinfection.
- Following social distancing protocol as is reasonable, given the procedure (e.g., not possible with blood draws)
- Minimizing the time of interaction between study personnel and subjects when social distancing is not possible
- Ensuring knowledge of and adherence to federal, state, local, and facility rules and guidelines
- Training the research team on risk mitigation protocols and any modifications made to the research plan, and documenting the training

Institutions and investigators must also consider the **financial burden** involved in implementing the above. The costs of masks, gloves, disinfectants, and potentially having to provide modified facility space are not insignificant, nor is the possible limited availability of those items.

The IRB must be trained to identify the current risks posed by COVID-19 and assess the need for any current or proposed face-to-face procedures in studies it reviews. IRBs and staff should be provided with the guidance issued by OHRP and FDA and advised that they do not have to review and approve screening procedures and other precautions that are required by facilities as these are not research procedures.

IRBs should consider whether:

- Risks to subjects have been minimized
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result
- The research plan includes adequate provisions for data safety monitoring
- The provisions to protect the privacy of subjects and to maintain the confidentiality of data are adequate
- Informed consent remains appropriate (e.g., the process, the elements, etc.)

If the criteria for IRB approval cannot be satisfied, then the research cannot be approved, or allowed to re-commence, until the criteria for approval are satisfied.

Tel: 347.862.9321
Fax: 347.862.9323
www.thehrpconsultinggroup.com

The IRB staff and IRB must be prepared for a wave of submissions as investigators seek to resume research and to initiate new research. Investigators should be advised of such and asked in advance for their patience. Institutions and IRBs may need to establish processes for the prioritization of submissions so that the work is manageable, and the system does not get bogged down.

DOCUMENTATION:

The steps taken by institutions, investigators, and IRBs, and the reasons for these actions, should be carefully documented. Policies and procedures may need to be reviewed and updated to ensure accurate description of the HRPP moving forward.

SUGGESTIONS ON COMMUNICATION WITH INVESTIGATORS:

Institutions and IRBs should proactively communicate with investigators about the possible resumption of research activities and what investigators should consider and will need to do before doing so. Any modifications to policies, procedures, and workflow, even temporarily, should be communicated to the research community by way of e-mail, website update, or whatever means are available to ensure that the research community remains informed.

Investigators should be encouraged to contact the HRPP/IRB office if they have questions or are uncertain regarding how to proceed with a research proposal or manage an issue related to the conduct of research during and after the pandemic.

RESOURCES:

- HRP COVID-19 Information: https://thehrpconsultinggroup.com/covid-19/
- CDC Coronavirus Disease 2019 Guidance Documents
- CDC Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes