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# THINK ABOUT…

## Impact of COVID-19 on IRB Staffing and Membership

**INTRODUCTION:**
With the current COVID-19 pandemic, 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:**
During this public health emergency, HRP has observed that institutions are increasingly furloughing 'nonessential personnel' and diverting resources, including equipment and personnel, to the COVID response. These diversions and furloughs may include both HRPP/IRB staff and IRB members and are straining the capacity of HRPPs and IRBs in many ways, including the ability to:

- Provide timely review of new protocols (including protocols directly related to COVID);
- Ensure that the IRB has the appropriate expertise available among its membership, or through consultation, to review the research before it;
- Achieve and maintain quorum and satisfy other regulatory requirements for IRB membership and function;
- Provide guidance to the research community as they face challenges unlike any they have experienced before;
- Ensure that subjects are informed of changes to research and other significant new information;
- Ensure that there is adequate safety monitoring of subjects; and
- To otherwise provide meaningful oversight of research to ensure the protection of human subjects.

HRPPs/IRBs in clinical organizations are also navigating the management of protocols that were uncommon prior to the pandemic, such as large scale Expanded Access Protocols, as well as the review of clinical trials without the benefit of data that are typically generated during the normal investigational product development cycle. Such data support the IRB's required analyses, e.g., risk/benefit, risk minimization, etc., and the information to be provided in informed consent.

Even with full staffing for the HRPP/IRB, and no loss of IRB membership, the ability to conduct 'normal' business may be at least partially impacted by the inability of some members to adapt to new technology used to conduct meetings via a virtual format. It is essential for there to be sensitivity to this matter, and ensure all members are properly educated,

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and that specific processes are put in place for holding virtual meetings (see, e.g., https://thehrpconsultinggroup.com/wp-content/uploads/2020/04/Conducting-Virtual-IRB-Meetings-Think-About.pdf).

To combat these issues, institutions may consider:

a) Providing a stipend to support the on-going participation of IRB members who have been furloughed or who are otherwise challenged in their ability to participate as a result of the public health emergency.
b) Use of personnel who have not been furloughed to assist with the daily operations of the HRPP and IRB, while ensuring that these individuals are trained and supervised by experienced personnel and do not have a conflicting interest that may impact their ability to be impartial.
c) Temporarily paring down IRB membership, reassigning some full members to alternate membership, and/or merging IRB panels so that IRBs remain duly constituted (see OHRP and FDA requirements for IRB membership), but 'streamlined', allowing for submissions to be handled more efficiently via the ability to quickly convene meetings with easier quorum requirements. Consideration should be made to include some of the IRB's more experienced members, with a foundation of regulatory knowledge, among the full membership, and to pull-in alternate members and consultants as needed to ensure expertise. These benefits must be weighed against the potential risk that IRB members may choose not to return to the IRB, or to full membership, once the public health emergency has ended.
d) Temporarily ceding new research to an external IRB. This would remove some of the immediate strain on the local IRB, allowing the IRB to focus on ensuring adequate human subject protections for existing research while still enabling the institution to facilitate research directly related to the public health emergency. That being said, the institution would need to understand that ceding review to an external IRB does not mean it is ceding its responsibility in other areas of the HRPP relating to that study (training, monitoring, COI, privacy, etc.). Unless the research being ceded is funded, there will be financial costs to consider for the use of an outside IRB. This must be weighed against the institution's desire to engage in new research including that directly related to COVID-19.

**DOCUMENTATION:**
Solutions, either temporary or permanent, must be documented in detail 'for the record'. If permanent, policies and procedures will need to be reviewed and updated to ensure accurate description of the HRPP moving forward. When relying upon an external IRB, reliance agreements will need to be executed and maintained, and procedures will be needed to identify, track, and maintain institutional oversight of these studies.

**SUGGESTIONS ON COMMUNICATION WITH INVESTIGATORS:**
Whenever policies and procedures are modified, even temporarily, notice should be disseminated to the research community, by way of e-mail, website update, or both.

Researchers 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 the pandemic.

**RESOURCES**

- HRP COVID-19 Information: https://thehrpconsultinggroup.com/covid-19/