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THINK ABOUT…

Implementing a COVID-19 Research Triage Process

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:
Many institutions have, or are considering, setting up a process to ensure that the escalating amount of research that is being proposed to combat or study COVID-19 is safe, effective, feasible, and the best use of resources at the institution.

What to consider: the establishment of a means to triage proposed COVID-19 research via a process that would precede, or be conducted in conjunction with, IRB review. Key input would be required for effective assessment, including:

- Infectious disease experts - for assessment or scientific merit and risk minimization
- Appropriate institutional representatives - for knowledge regarding:
  - The ever-changing landscape at the federal, state, and local levels (e.g., shelter-in-place orders, medical licensure considerations, HIPAA, etc.)
  - Resource allocation and whether the resources necessary for the safe conduct of the research (e.g., PPE, support staff, etc.) are available and likely to remain so
  - Finance – to provide input on budget and funding
- Front-line providers involved with the care of COVID-19 patients – for assessment of whether the proposed research would potentially interfere with the provision of essential clinical care
- Biohazard experts- for containment considerations, handling and shipping specimens, etc.
- Informatics experts – for evaluation of data strategies and whether data points can be gathered by alternate means

Potential Strategies:

- Creation of a COVID-19 Research Triage Committee, with membership including individuals with expertise as defined above

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- Creation of a sign-off process with dissemination of proposals to individuals such as those above (as appropriate to the research – e.g., research that doesn't involve direct contact with patients or specimens would not necessarily have to be reviewed by front-line providers and biohazard experts)
- Department Chair level review prior to engaging the above – so that the Department Chair can prioritize and only move forward the highest-priority research from their perspective

Challenges:

- Need to act as efficiently as possible to avoid delays in important research
  - Consider parallel reviews instead of sequential
  - Consider review processes that don't necessitate actually convening the committee
- Staffing the process
  - Consider whether there are staff or students whose job responsibilities have decreased as a result of the pandemic and who may be able to manage the review process remotely
- Need to "keep it simple" to avoid adding burden during an already challenging time
  - Consider whether tech "solutions" are helpful or more cumbersome than necessary – can this review process be managed by email, document sharing, or another simple tech solution?
- Availability of the appropriate experts during a time when these very experts are being stretched very thin
  - Consult in advance with those that would be involved and their leaders – how can we do this important work in a way that will work for you?

DOCUMENTATION:

Consider:

- Documenting the establishment of the committee or other review process, its purpose, and authorities (e.g., in a memo from an appropriate high-level leader (e.g., SVP for Research))
- Documenting the processes that will be used to manage the review process and communicate outcomes – recognize that these may need to be revisited as you gain 'real-world' experience
- Documenting the review process for each proposal (e.g., what was submitted, what questions went back to the investigator and the investigator response, review outcome (e.g., approval, disapproval, tabled for now as lower priority or until resources are available, etc.) and the basis for the decision)

ENSURING COMPLIANCE:

- The review process should include consideration of whether the proposal complies with federal, state, and local orders, requirements, and restrictions (e.g., shelter-in-place orders, non-essential businesses and workers orders, COVID screening requirements, facility access restrictions, CDC guidelines, etc.)
- The review process should include consideration of privacy and confidentiality rules, policies, and flexibilities that may have been extended related to such (e.g., OCR HIPAA Bulletins)

SUGGESTIONS ON COMMUNICATION WITH INVESTIGATORS:

Transparency and ease of navigation will be critical, consider use of email communications and a website dedicated COVID-19 information for researchers to communicate:

- The need for and purpose of the review process, and its leadership authorization

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- The overall process for approval of COVID-19 research and whether its sequential or if certain components are parallel (e.g., Department Chair to COVID-19 Research Triage Committee to Ancillary Committees (e.g., COI, Radiation Safety, Biosafety) to IRB vs. Department Chair then COVID-19 Research Triage Committee, Ancillary Committees, IRB in parallel)
- How to submit for review
- Possible review outcomes and how outcomes will be communicated
- Anticipated timelines
- Point(s) of contact
- Any resources available to assist with process

RESOURCES

State and local orders during COVID-19 – this will vary by state and locality, most states have websites dedicated to COVID

- Telehealth and HIPAA: https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
- HIPAA, Civil Rights, and COVID-19: https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html?language=es
- COVID-19 Information From the FDA: https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (March 27 update): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
- Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding: https://grants.nih.gov/grants/natural_disasters/corona-virus.htm
- NSF Coronavirus Information: https://www.nsf.gov/news/special_reports/coronavirus/
- CDC Interim Biosafety Guidelines for COVID-19 Specimens: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
- AAHRPP Guidance on HRPP Response to COVID-19: https://admin.aahrpp.org/Website%20Documents/Guidance%20for%20Accredited%20Organizations%20on%20COVID-19%20(2020-03-23)%20(for%20distribution).pdf
- PRIM&R COVID-19 and Coronavirus: Updates for the Oversight Community: https://blog.primr.org/covid-19-and-coronavirus-updates-for-the-oversight-community/