CONSULTING GROUP
Research Ethics and Compliance
Management Solutions
Tel: 347.862.9321
Fax: 347.862.9323
www.thehrpconsultinggroup.com

THINK ABOUT…

Research with COVID-19 Data and Biospecimens

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:
In their quest to search for safe and effective prophylaxis and treatments to bring this pandemic to an end, many researchers are in need of data and/or biological specimens from patients afflicted with, and/or recovered from, COVID-19. During this time of increasingly limited resources, institutions should assess what processes need to be put into place that will be most efficient, and facilitative, to support these efforts.

What to consider:

Two main variables that will impact institutional processes include:

- Researchers' need for data/biospecimens generated or collected for clinical care vs. research-specific acquisition of data/biospecimens, and
- need for identifiable data/specimens (e.g., for tracking patients longitudinally)

For example:

- **Researchers requiring data/specimens already collected for clinical reasons:** The Institution's standard process for researcher access to clinical data (e.g., from medical records) and clinical biospecimens (e.g., from Pathology) may be followed. Of concern may be the availability of certain biospecimens (e.g., blood from recovered patients) for research, and the need for the institution to triage requests. See HRP Think About-Research Triage Process for further discussion on this topic.

  If the data or specimens are provided by the institution to the researcher in such a manner that the identities of the patients are, or may readily be, ascertained by the investigator or associated with the information, then the IRB Office will first need to review the proposed research for issuance of an exemption or IRB approval. If that is not the case, the patients may not be considered 'human subjects' under the definition at 45 CFR 46.102(e) and IRB approval or exemption would not apply. See OHRP's Guidance on Coded Private Information or Specimens Use in Research for more information. However:

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- Institutional policies may require that the HRPP/IRB Office confirm that the activity is 'not human subjects research' in order for the researcher to be able to access the data/specimens. Variables that the HRPP/IRB Office might consider include:
  - The relationship of the researcher to the subjects (e.g., do they know who some or all of the subject are, or might they recognize their own patients and colleagues in the data?),
  - The number and nature of requested data points,
  - Who will generate the data/gather the biospecimens (e.g., the research team or a third party otherwise uninvolved in the research),
  - Whether genomic data will be generated,
  - Whether the research includes the combination of data from multiple sources (e.g., public records)
- When FDA regulations apply, the identifiability of data/biospecimens does not inform the IRB determination. Rather it is whether the activity is a clinical investigation involving one or more human subjects using the FDA definitions. For example, for research involving medical devices, a human subject is an individual on whom or on whose specimen an investigational device is used or as a control [21 CFR 812.3(p)]. Note that this definition does not include or imply that the specimens are "identifiable".
- Although the activity may not involve 'human subjects' according to federal regulations governing human research, HIPAA regulations may apply to the use or disclosure of health information that does not meet that regulations' threshold for being de-identified.

- **Researchers proposing to collect data and specimens specifically for research:** For these activities, the individual needs of the researchers for specific research data and biospecimens must be weighed against the clinical needs of the patient, the 'value' and possible clinical utility of the patients' biospecimens (e.g., from those cured of COVID-19), and the resources that the research will consume, including those required for IRB review and oversight. Processes should be considered whereby:
  - As above, a COVID—19 research triage procedure or committee can put into place to address merit, resources, impact on clinical care, and patient privacy (how many research studies should be permitted for presentation to the patient for their possible consent to participate?)

- **For both of the above:** An institutional COVID-19 database/biospecimen repository could be considered rather than permitting individual COVID-19 data/biospecimen collections not associated with a clinical trial. One repository submission to the IRB can be generated, along with a single consent (and HIPAA authorization that addresses future use of the data) for the patient to consider.

  The bank/repository can propose to retain identifiers, but include in their IRB submission that the PI/Director and designees would serve as a 'gate-keeper' (in consultation with any other triaging processes in place) to ensure that investigators do not receive data, or biospecimens labeled with identifiers, beyond that allowed under a Limited Data Set. An agreement for use of repository data/biospecimens could include the elements required for a valid Data Use Agreement under HIPAA, a prohibition on the release of additional identifiers or the key to enable re-identification by the repository to investigators, and a prohibition on investigators re-identifying information (e.g., by combining with or comparing to other data sources).

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The application to obtain data/biospecimens from the repository could include screening questions to help determine whether submission to the IRB would be required and to screen for other requirements that may be applicable to the research (e.g., FDA regulations, biosafety review, COI review, requirements associated with funding agencies, etc.).

The combination of a vetting process for COVID-19 research and an institutional data/biospecimen repository would facilitate COVID-19 research, reduce the overall burden of such research on institutional resources, and help insulate patients and their loved ones from being approached multiple times by multiple researchers during a period of extreme stress.

Further considerations:

- Exception processes for requests that fall outside of the scope of the repository or that necessitates the use of data that includes more identifiers than a limited data set and/or for biospecimens labeled or associated with identifiers.
- Need for proper storage/containment of biospecimens which may require input from biosafety specialists at the Institution. See https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html for additional information.
- Application to NIH for a Certificate of Confidentiality to protect the banked data and specimens from improper disclosure (funding through NIH is not required): https://grants.nih.gov/policy/humansubjects/coc.htm
- Data sharing obligations that may apply to future research (e.g., because of the funding source) and obtaining informed consent for such
- HIPAA requirements (e.g., authorization, security, etc.)
- State law (e.g., some states require additional licensure to operate a tissue repository)

DOCUMENTATION:

Standard institutional policies and procedures may be followed for most activities above. A submission to the IRB for COVID-19 database and biospecimen repository should include all required documentation to secure IRB approval. The PI of the repository will need to develop a relevant application for researchers to gain access to the data/biospecimens, as well as a review procedure, including timelines, to ensure transparency of the processes. Databases and repositories must keep careful records of their banked material, including identities of researchers to whom such materials were distributed, and under what conditions. When a Certificate of Confidentiality applies (NIH recommended for repositories), recipients of data/biospecimens must be informed of the Certificate and their obligations under law. This could be incorporated into the user agreement so that it is documented.

This documentation should be maintained in accordance with applicable record retention requirements.

SUGGESTIONS ON COMMUNICATION WITH INVESTIGATORS:

Whenever policies and procedures are modified, even temporarily, notice should be disseminated to the research community. Such an example would be the establishment of a COVID-19 database/repository, and subsequent availability to researchers of data and biospecimens from COVID-19 patients through an identified process. This notice should also be readily available for researchers (e.g., on a webpage known to researchers for such information, within the IRB electronic platform, etc.).

Researchers should be encouraged to contact the HRPP/IRB office if they have questions or are uncertain regarding how to proceed with a COVID-19 research proposal.

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RESOURCES

- HRP's COVID-19 Information: https://thehrpconsultinggroup.com/covid-19/
- OCR's Webpage: https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html
- OCR's Guidance Regarding Methods for De-identification of PHI in Accordance with the HIPAA Privacy Rule
- OCR's Guidance on HIPAA and Individual Authorization of Uses and Disclosures of PHI for Research
- CDC Interim Biosafety Guidelines for COVID-19 Specimens: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
- Certificates of Confidentiality (CoC): https://grants.nih.gov/policy/humansubjects/coc.htm
- PRIM&R COVID-19 and Coronavirus: Updates for the Oversight Community: https://blog.primr.org/covid-19-and-coronavirus-updates-for-the-oversight-community/
- 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 CDER Coronavirus (COVID-19) Webpage: https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs?utm_campaign=SBIA%20Covid%20webpages&utm_medium=email&utm_source=Eloqua
- 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/