American Health Law Association
The Year in Review Topic Team Outlines

The pace of development in health care and health law speeds up each year. 2020 saw more developments than usual, in part because of the COVID-19 pandemic and the new statutes, regulations and agency guidance issued in response. To help AHLA members keep up to date with these developments, AHLA is providing this extra resource to accompany the Year in Review slides.

We have assembled teams of outstanding lawyers for each health care topic, who have submitted outlines of the significant developments in their areas of expertise. This effort is newly underway, so many of the topic teams did not have the opportunity to cover all 2020 developments. Nonetheless, we think this will be an outstanding resource for AHLA members.

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As the Year in Review speakers, we greatly appreciate the Topic Teams' efforts to capture these recent developments, which were enormously helpful to us in preparing for this talk.

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unemployment. The District Court disagreed, finding that neither agency met the "good cause" standard required under the APA to forego the notice and comment procedure prior to implementing a new regulation. The District Court also found that there was no rational relationship between the unemployment caused by the COVID-19 pandemic and the employment of H-1B workers.

The Court listed several factors as reasons for reaching this conclusion, specifically: (1) the fact that the agencies waited more than six months to issue the rules they alleged were necessary due to the COVID-19 related unemployment; (2) the DHS rule first appeared on the agency's regulatory agenda in the fall of 2017; and (3) even the rules themselves indicated that these measures should have been taken years ago. The Court ultimately found that the Agencies did not demonstrate good cause for bypassing the required notice and comment period.

VIII. LIFE SCIENCES AND CLINICAL RESEARCH

A. Research Integrity and Misconduct

Author: Kate Gallin Heffernan, Epstein Becker & Green, P.C.

Research integrity faced unique pressures in 2020, in part due to the rapid response of researchers to the COVID-19 pandemic, and corresponding rush to publish related manuscripts.

1. ORI Leadership

With respect to the regulation of research misconduct in the United States, the Office of Research Integrity (ORI), responsible for the enforcement of integrity in the context of research supported by Public Health Service funds, attempted to rebuild its leadership. The leadership at ORI has come under scrutiny in recent years, with reports of internal turmoil leading to the departure of key staff and leadership turnover.

In March 2020, the Office of the Assistant Secretary for Health (OASH) appointed Elizabeth Handley permanent Director of ORI, following her service as interim Director since August 2019. Wanda Jones, who had served as interim Director in between Kathy Partin and Ms. Handley, was also appointed associate director of research and scientific integrity.

2. Request for Information Regarding Activities that Foster Research Integrity

On October 19, 2020, ORI published a request for information (RFI) regarding activities that "foster research integrity and promote the responsible conduct of research under 42 CFR Part 93." The stated purpose of this RFI is to assist ORI in conducting outreach and developing educational resources for the grantee community. Responses were due on December 18, 2020.

3. HHS Administrative Actions

Administrative actions on the grounds of findings of research misconduct were imposed by HHS on ten individuals in 2020.

4. Misconduct During a Pandemic – the Dangers of Expediency and Opportunity?

The understandable time-pressure on researchers in connection with the COVID-19 pandemic not surprisingly resulted in vigorous debate among the researcher and medical journal communities as to the risks of rushing to publish during a public health emergency. One notable instance of questioned science involved the Illinois-based company Surgisphere, which was responsible for provided the data underlying a number of COVID-19 related publications, including a May 22 article in The Lancet stating that hydroxychloroquine was associated with increased risk of death in hospitalized patients with COVID-19. The paper had immediate and far-reaching impact on pandemic research and clinical recommendations for COVID-19 treatments, including influencing the World Health Organization to suspend testing of hydroxychloroquine. The reported research was supposedly based on a large database of medical records maintained by Surgisphere. However, the paper came under scrutiny leading to questions over whether Surgisphere's database even exists, particularly after the company's founder refused to permit an audit of the database. The Lancet paper and another paper in the New England Journal of Medicine, also based on Surgisphere data, that found no increase of risk for COVID-19 patients taking ACE-inhibitors, were both ultimately retracted. The notoriety of the Surgisphere scandal contributed to a larger dialogue around how best to balance scientific expediency with integrity in the context of a public health emergency.

B. Conflicts of Interest and Undue Foreign Influence in Research

Author: Kate Gallin Heffernan, Epstein Becker & Green, P.C.

2020 saw continued focus by the NIH, DOJ, FBI and other federal agencies on combatting the threat of foreign undue influence to U.S. research efforts. This enforcement focus began in March 2018, when the NIH issued a notice reminding the researcher community that *all* financial interests received by a U.S. investigator from a foreign institution of higher education or foreign government must be disclosed to NIH in accordance with the Public Health Service financial conflicts of interest regulations, 42 CFR Part 50, Subpart F, which require disclosure of investigator significant financial conflicts of interest. This was followed by a statement by Francis Collins, Director of NIH, in August 2018 on the NIH's commitment to protecting U.S. research from undue foreign influence, during which time the NIH-grantee community also began to receive "Dear Colleague" letters alerting the regulated community to the NIH's concerns and anticipating follow-up inquiries from the Office of Extramural Research (OER) related to specific researchers or submissions. The ACD Working Group on Foreign Influences on Research Integrity was formed, issuing its first report in December 2018. On July 10, 2019, the NIH issued NOT-OD-19-114 to remind grantees of the obligation "to report foreign activities through documentation of other support, foreign components, and

financial conflict of interest to prevent scientific, budgetary, or commitment overlap." The U.S. Senate Permanent Subcommittee on Investigations subsequently issued a report in November 2019 exploring the specific threats to U.S. research posed by China's talent recruitment programs.

The specific concerns related to undue foreign influence on U.S. researchers and the potential theft of U.S. intellectual property have revitalized institutions' focus on how their existing conflicts of interest policies and processes address the topic of foreign interests. Highlighted developments and cases of note in 2020 are discussed below. In response to the government's enforcement efforts, the regulated community has been engaged in the development of best practices related to its education of the researcher community and implementation of compliance programs and processes to identify potential instances of undue foreign influence in a timely manner.

1. Submission of FCOI Policy to NIH

NIH grantees are required by NIH policy to maintain policies on financial conflicts of interest that comply with the PHS FCOI regulations. Pursuant to NOT-OD-21-002, grantees are required, effective November 12, 2020, to submit their financial conflicts of interest policies to the NIH through ERA Commons. In light of the required systems upgrade, grantee institutions were given until December 1, 2020 to comply. This requirement increased the importance of NIH grantees ensuring that their conflicts of interest policies and procedures adequately and explicitly address foreign interests.

2. Enforcement Actions of Note

- *Department of Justice Settlement with the Van Andel Research Institute*

The close of 2019 saw a significant ($5,500,000) settlement between the Department of Justice and the Van Andel Research Institute (VARI) related to allegations that VARI violated the False Claims Act by failing to disclose other support in the form of Chinese government grants supporting two of its research scientists.

- *Florida State Legislature Commences Probe into Foreign Influence on Florida Researchers*

Florida legislators announced a state-level probe, focused on public research institutions, to run in parallel with federal efforts. The initiative was motivated in part by the resignation in December 2019 of Moffitt Cancer Center's Chief Executive Officer and Director, along with several researchers, following an internal investigation related to conflicts of interest and undue foreign influence connected to the individuals' participation in China's Thousand Talents Program. Although government research funding is largely federal, this development illustrates the enforcement role state governments and agencies may nonetheless play vis-à-vis foreign undue influence and conflicts of interest.

- *Researcher Charles Lieber Charged by Department of Justice (January 28, 2020)*

On January 28, 2020, the Department of Justice charged nanoscientist Charles Lieber, the former Chair of Harvard University's Chemistry and Chemical Biology Department, with making a materially false, fictitious and fraudulent statement in connection with his involvement in China's Thousand Talents Plan and affiliation with Wuhan University of Technology. He was subsequently indicted on June 9, 2020 for making false statements, which was superseded on July 28, 2020 to include filing false federal tax returns. Dr. Lieber has sued Harvard to recoup the costs of his legal defense, which remains active.

- *Researcher Xiao-Jiang Li Convicted of Federal Tax Fraud (May 11, 2020)*

Xiao-Jiang Li joined the Chinese-government Thousand Talents Program in 2011, while a researcher at Emory University. He was dismissed from Emory, along with his colleague and wife Shihua Li, in May 2019, following an internal investigation by Emory into their failure to disclose foreign research funding and work they performed on behalf of Chinese institutions and universities. On May 8, 2020, Xiao-Jiang Li pleaded guilty to filing a false tax return, in connection with his failure to report foreign income deriving from his work in China, illustrating another legal hook that the government has employed in these cases.

- *Researcher Song Guo Zheng Pleads Guilty to Lying on Federal Grant Applications to Develop Scientific Expertise for China*

Song Guo Zheng, a former rheumatology professor and researcher at the Ohio State University, pled guilty on November 12, 2020 to lying on grant submissions to the NIH in connection with his failure to disclose his participation in the Chinese Talent Plans and collaboration with a Chinese university. Zheng was charged with using of NIH funds to develop China's expertise in rheumatology and immunology, and was arrested while attempting to depart the United States to China with proprietary research information.

3. Update from the ACD Working Group on Foreign Influences on Research Integrity

The Advisory Committee to the NIH Director Working Group on Foreign Influences on Research Integrity issued an update on June 12, 2020, describing the NIH's efforts thus far to combat foreign undue influence in research. Significant statistics include:

- Thus far, 399 grantees have come to NIH's attention. Of those 399, 251 warranted further scrutiny, 76 were exonerated, and 72 cases are still pending.
- NIH has sent letters to 87 institutions raising questions about behavior of 189 scientists. Of those 189:
  - 54 subsequently lost their jobs
  - 70 were found to have violated institutional requirements
  - 102 failed to disclose their participation in a foreign talent recruitment program (*e.g.*, China's Thousand Talents Program)

- 133 failed to disclose a grant from a foreign entity
- 71% of the 87 institutions that received letters acknowledged noncompliance.

4. Undue Influence as Research Misconduct?

An on-going debate regarding the most appropriate way to regulate and respond to instances of undue foreign influence has included an argument that allegations of activities in furtherance of foreign interests in U.S. research should be evaluated within the same framework as allegations of research misconduct. A December 2019 JASON report commissioned by the National Science Foundation supported this approach. It remains to be seen whether there is any consensus or regulatory action in furtherance of this approach.

5. GAO Report

In December 2020 the Government Accountability Office issued a report to the to the Chairman, Committee on Finance, of the United States Senate, entitled *Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence*, which identified gaps in select U.S. agency and institutional policies on foreign influence in research and made recommendations on how funding agencies should address the issue moving forward.

C. FDA: Devices

Author: Kate Gallin Heffernan, Epstein Becker & Green, P.C.

Much of the FDA's oversight activities in the context of devices this year related to issuing Emergency Use Authorization for various diagnostic tests for the SARS-CoV-2 virus and the presence of antibodies; the FDA regulation of laboratory developed tests, in particular, is discussed in more detail below. Additional guidance specific to the regulation of devices in the context of the COVID-19 public health emergency included:

- Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID-19 Public Health Emergency Guidance for Industry
- And several web-pages dedicated to FDA regulation of Personal Protective Equipment during the pandemic, including:
  - FAQs on face masks and respirators
  - Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)
  - Emergency Use Authorizations of certain PPE

More specifically in the context of device trials, the FDA issued the following guidance, applicable in both the drug and device trial context:

- Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry

A digest of recent FDA device guidance can be found here.

1. Laboratory Developed Tests

The FDA's regulation of laboratory developed tests (LDTs) – in vitro diagnostic tests that are designed, manufactured and used within a single laboratory – has been an evolving quagmire over the past decade and 2020 continued to complicate FDA's enforcement approach, which, as recently as 2017, remained under consideration by the FDA as it explored a possible partnership with CMS, the agency responsible for regulating laboratories under the Clinical Laboratory Improvement Amendments (CLIA).
Of particular relevance in 2020, many of the new diagnostic tests granted Emergency Use Authorization (EUA) by the FDA for purposes of diagnosing the presence of or antibodies to the SARS-CoV-2 virus have been LDTs. Early in the pandemic, FDA issued guidance for laboratories and commercial manufacturers of diagnostic tests for SARS-CoV-2, outlining various approaches to facilitate the availability of new diagnostic testing to combat the pandemic. This includes permitting certain tests, not including home collection tests, to be used once validated and while awaiting FDA's determination on an EUA submission. It also allowed states to assume the authorization responsibility for CLIA-certified labs operating within the state, obviating the need for FDA authorization.

More recently, in August 2020, HHS issued a statement in which it stated that the FDA would no longer review LDTs. This statement was not limited to LDTs being developed in connection with the COVID-19 pandemic; no LDTs require pre-market approval under HSS' new interpretation. This policy does not apply to direct-to-consumer tests. The accompanying FAQs indicate that a laboratory might still seek an Emergency Use Authorization (EUA) for an LDT in order to trigger coverage under the Public Readiness and Emergency Preparedness Act (the "PREP Act") to avail itself of immunity.

Following HHS' statement, FDA took the position in early October that it would no longer be reviewing applications for EUAs for LDTs, and would be prioritizing review of other testing technologies like point of care and home testing. However, it was then brought to Assistant Secretary of Health Giroir's attention that this downstream consequence of the HHS rescission order (*i.e.* FDA declining to review voluntarily submitted EUAs) would be the ineligibility of such tests for PREP Act immunity (this was driven by Senator Amy Klobuchar, after the University of Minnesota raised the issue). Consequently, Assistant Secretary Giroir instructed the FDA in mid-November to review voluntary EUA submissions for LDTs in a "timely" manner, notwithstanding the HHS rescission order. (See additional reporting here.) Although there were reports that Secretary Giroir was being pressured to extend PREP Act coverage to LDTs regardless of FDA authorization administratively, no PREP Act declaration or amendment to that effect occurred.

There is ambiguity as to whether LDTs that are in use but awaiting an FDA EUA (*e.g.*, CLIA labs that, under FDA's policy, are permitted to deploy validated LDTs following

application to the FDA for emergency use authorization and while awaiting issuance of the EUA) qualify as "covered countermeasures" under the PREP Act. Without the issuance of an EUA, there is risk that a "Covered Person," as defined in the PREP Act, is not shielded from liability. Similarly, if FDA had continued to decline review of LDT EUA applications (which it has now been instructed not to do), there is risk regarding whether the use of an LDT for which an EUA submission was made would be covered by the PREP Act. As a general matter, it remains to be seen how any claim for immunity pursuant to the Declaration Under the PREP Act for Medical Countermeasures for COVID-19 is adjudicated.

2. CARES Act

Section 3121 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amended the Federal Food, Drug, and Cosmetic Act by adding a new section 506J (21 U.S.C. 356j) to require device manufacturers to notify the Secretary of Health and Human Services of potential and actual device shortages occurring during the COVID-19 public health emergency. This includes permanent discontinuances or manufacturing interruptions caused by the pandemic. The Center for Devices and Radiological Health (CDRH) issued guidance, updated in November 2020.

D. COVID-19 and Research

Authors: Clint Hermes, Whitney Mosey, Elaine Naughton, and Angelique Salib, Bass, Berry & Sims PLC

1. NIH Guidance on Clinical Trials

On March 16, 2020, the National Institutes of Health (NIH) released a notice titled, "Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19." The purpose of the notice is to provide guidance outlining flexibilities to recipients conducting NIH-funded clinical trials and human subject studies impacted by the public health emergency (PHE). NIH's foremost concern is the safety and welfare of research participants and staff. To that end, NIH encourages all recipients to consult with their IRB on measures to protect participants and staff (*e.g.* limiting study visits, flexibilities for laboratory testing or imaging and suspending travel). The notice also outlines certain flexibilities for the submission of late financial and progress reports, and extending final budget periods one time for up to 12 months without requesting prior NIH approval. Additionally, the guidance addresses flexibilities for unanticipated costs due to impacts of the PHE. The NIH regularly updates the FAQs to the guidance.

On October 26, 2020, NIH issued guidance titled "Considerations for New and Ongoing Human Subjects Research During the COVID-19 Public Health Emergency." NIH acknowledges in this guidance that applicant and recipient institutions may need to exercise flexibility as they navigate the current PHE and that some research may need to slow or pause altogether as hospitals and clinics prioritize patients, work to prevent exposure and manage supply chain interruptions. NIH encourages institutions to engage with their IRB to devise and implement necessary changes. The guidance reminds

investigators of regulations that allow the implementation of changes before obtaining prospective IRB approval in situations when necessary to "eliminate apparent immediate hazards to the subject" (see, 45 CFR § 46.108(3)(iii)).

2. OHRP Guidance on Clinical Trials

In April of 2020, the Office for Human Research Protections (OHRP) of the US Department of Health & Human Services (HHS) issued its Research Guidance on Coronavirus. The guidance focuses on the regulatory requirements at 45 CFR part 46, which pertain to the protection of human subjects. Specifically, OHRP discusses four issues with respect to the intersection of human subjects research and the PHE:

- Public Health and Clinical Activities. Actions taken for public health or clinical purposes but not for research purposes are not research procedures and therefore do not require IRB approval before being implemented. Additionally, some types of public health surveillance activities are explicitly excluded from the Revised Common Rule at 45 CFR § 46.102(l)(2) (*e.g.*, the collection and testing of information or biospecimens, conducted supported, requested, ordered, required, or authorized by a public health authority). However, FDA regulations may still apply if the activity uses an investigational *in vitro* diagnostic device. Finally, OHRP reminds investigators that the human subjects regulations allow for legally required reporting of a research subject's COVID-19 test results, even if a Certificate of Confidentiality is in place or if such disclosure would be inconsistent with the study's consent form.
- Research Changes to Eliminate Apparent Immediate Hazards. Changes to approved research may be implemented prior to IRB review and approval if the changes are necessary to eliminate apparent immediate hazards to the subject (see, 45 CFR § 46.108(a)(3)(iii) of the Revised Common Rule). For example, non-essential study visits might be cancelled or postponed. While prior IRB approval is not needed prior to implementation of these changes, OHRP recommends that investigators report the changes to the IRB when possible.
- Proposing and Reviewing Study Changes. IRBs may use an expedited review procedure to review study changes if the study changes are minor (see, 45 CFR § 46.110(b)(1)(ii) of the Revised Common Rule).
- Whether Suspensions of Research Must be Reported. OHRP reminds the research community that only IRB suspensions or terminations of approved research are required to be reported to OHRP; if an investigator or institutional office suspends or terminates approved research, such actions do not need to be reported (see, 45 CFR § 46.113).

OHRP also references its prior guidance from 2018 as potentially applicable to the PHE, "Effects of Disasters on Human Research Protections Programs Guidance." OHRP believes this 2018 guidance indicates that OHRP will take into account the emergency circumstances institutions are experiencing as a result of the PHE and will use flexibility in its decision-making. OHRP held a live webcast on April 28, 2020 regarding its 2020 PHE guidance and the slide deck from the webcast is available for review.

3. Single IRB Exception Determination

On October 8, 2020, OHRP issued an exception determination as permitted by 45 CFR § 46.114(b)(2)(ii). The exception determination states that certain categories of cooperative research supported or conducted by HHS and subject to the Revised Common Rule are not required to comply with the Revised Common Rule's single IRB mandate. Generally, the Revised Common Rule requires any institution located in the United States that is engaged in cooperative research (*i.e.*, projects that involve more than one institution) to rely upon approval by a single IRB. Due to the PHE, OHRP is exercising its discretion to issue an exception to the single IRB mandate on the basis that using a single IRB is not appropriate for this research context. OHRP believes that the PHE has created unprecedented burdens and disruption to the research enterprise, while still requiring urgent research responses that require flexible approaches. Specifically, the exception determination applies to cooperative research:

- That is ongoing or initially reviewed by the IRB during the PHE;
- Where reliance on a single IRB would not be practical; and
- For which the HHS division supporting or conducting the research approves the use of the exception.

OHRP provides examples of situations in which it may not be practical to rely on a single IRB for multi-site cooperative research:

- Trials for which timely administration of an intervention for COVID-19 is paramount but research sites cannot be identified in advance due to uncertainties in outbreaks, or where institutions without existing reliance agreements (especially in underserved areas) may face delays in starting a trial while the reliance agreement is being negotiated.
- Trials in which the lead site or IRB is unable to provide oversight as a result of disruptions in operations caused by the PHE, but other sites can continue.
- Trials in which a federal research agency wants to participate as a research site with a non-federal site but is legally prohibited from agreeing to certain terms in reliance agreements as required by the non-federal site.

Note that this exception does not prevent and should not be construed to discourage the voluntary use of a single IRB in cooperative research that is subject to the Revised Common Rule.

On October 23, 2020, NIH issued a notice to the extramural research community on the implementation of OHRP's single IRB exception determination. For as long as OHRP's exception determination is in place, NIH will not require the use of a single IRB for NIH-funded research that qualifies for an exception and for which NIH also approves the exception. Recipients are required to submit an exception request to NIH, including justification as to why the study meets the exception criteria defined by OHRP.

4. FDA Guidance on Clinical Trials Generally

On March 18, 2020, the Food and Drug Administration (FDA) published guidance titled, "Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency, Guidance for Industry, Investigators, and Institutional Review Boards." The purpose of the guidance is to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity for the duration of the COVID-19 public health emergency (PHE). FDA expects sponsors, investigators and institutional review boards (IRB) to document their efforts to maintain the safety of trial participants and study data integrity. FDA also recognizes that protocol modifications may be required and documentation of the same is very important. The FAQs attached to the guidance provide a great deal of helpful information on research implementation challenges caused by the PHE and are updated regularly.

In June of 2020, FDA published nonbinding guidance titled, "Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency, Guidance for Industry." The purpose of the guidance is to recommend statistical considerations to address the impact of COVID-19 on meeting trial objectives for clinical trials during the duration of the PHE. Specifically, the guidance addresses considerations for analyzing primary and key secondary endpoints in a trial affected by COVID-19 (*e.g.*, trial participants not being able to visit clinical sites for endpoint assessments) to help ensure the trial provides interpretable findings with correct statistical quantification of uncertainty.

5. FDA Guidance on the Development of Drugs and Biologic Products

In May of 2020, FDA issued guidance titled, "COVID-19: Developing Drugs and Biological Products for Treatment or Prevention." The purpose of the guidance is to assist sponsors in the clinical development of drugs and biologic products with direct antiviral or immunomodulatory activity for the treatment or prevention of COVID-19. Specifically, the guidance describes FDA's recommendations regarding phase 2 and phase 3 trials, with a focus on populations, trial design, efficacy endpoints, and safety and statistical considerations for such trials. This guidance does not address the development of vaccines or convalescent plasma.

6. FDA Guidance on the Development and Licensure of COVID-19 Vaccines

In June of 2020, FDA issued guidance titled, "Development and Licensure of Vaccines to Prevent COVID-19." The purpose of this guidance is to describe FDA's recommendations regarding the data needed to facilitate clinical development and licensure of COVID-19 vaccines. Specifically, the guidance outlines an overview of key considerations to satisfy the regulatory requirements set forth in the investigational new drug application (IND) regulations at 21 CFR part 312 and biologics licensing regulations at 21 CFR part 601 for chemistry, manufacturing, and controls, nonclinical and clinical

data through development and licensure, and for post-licensure safety evaluation of COVID-19 preventative vaccines. With respect to clinical trials, FDA addresses issues related to trial populations, trial design, efficacy, statistical considerations, and safety considerations. The guidance played a significant role in harmonizing trial design across the major vaccine candidates and platforms.

7. FDA Guidance on Emergency Use Authorization for COVID-19 Vaccines

In October of 2020, FDA issued nonbinding guidance titled, "Emergency Use Authorization for Vaccines to Prevent COVID-19." The purpose of this guidance is to describe FDA's recommendations regarding the data and information needed to support the issuance of an emergency use authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (21 USC 360bbb-3) for an investigational vaccine to prevent COVID-19, including guidance on CMC, nonclinical data and information, clinical data and information, as well as administrative and regulatory information. Additionally, the guidance provides recommendations regarding key information and data that should be submitted to a relevant IND or cross-referenced master file prior to submission of an EUA request. Before an EUA is issued to a sponsor, FDA expects to convene an open session of FDA's Vaccines and Related Biological Products Advisory Committee to discuss whether the available safety and effectiveness data support issuance of an EUA. Further, FDA expects that following the submission of an EUA request and issuance of an EUA, a sponsor would continue to collect blinded, placebo-controlled data in any ongoing trials for as long as feasible and that the sponsor would work towards the submission of a biologics license application as soon as possible.

E. FDA: Drugs and Biologics

Authors: Clint Hermes, Whitney Mosey, Elaine Naughton, and Angelique Salib, Bass, Berry & Sims PLC

Given the widespread effects of the COVID-19 pandemic, the FDA largely focused in 2020 on addressing COVID-19 relief resulting in updated guidance, including vaccine development and emergency use authorization for vaccines as described above.

Given the world-wide focus on drug development in response to the pandemic, the FDA also focused on providing industry guidance for research and clinical trials of drugs and biologics. In December 2020, the FDA issued final guidance: *Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products*. The guidance was issued in part to satisfy a mandate under Section 3021 of the 21st Century Cures Act and provides guidelines on FDA and sponsor interactions for complex innovative design proposals for trials proposing to provide evidence of effectiveness. The guidance provides examples of clinical trial designs the FDA may consider to qualify as complex innovative trial design and provides recommended types of detailed quantitative and qualitative information to submit in tandem with proposals to facilitate effective communication between sponsors and the FDA. The role of simulations in clinical trial design and planning are also discussed.

In addition, as noted above, the FDA issued guidance for industry, investigators, and IRBs in March 2020, updated December 4, 2020: *FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency*, which provides broad considerations to enhance safety of trial participants, comply with good clinical practices, and maintain trial integrity during the COVID-19 pandemic.

The FDA issued guidance in November 2020: *Adaptive Designs for Clinical Trials of Drugs and Biologics*, addressing clinical trial designs permitting prospectively planned modifications based on gathering data from trial subjects. The guidance provides principles for designing, conducting and reporting adaptive clinical trial results to sponsors and applicants submitting various types of drug or biologics applications.

In the same month, the FDA also issued guidance: *Enhancing the Diversity of Clinical Trial Populations*, which addresses certain eligibility criteria, enrollment practices and provides trial design guidance to increase the enrollment of historically underrepresented groups in clinical trials for new drug or biologics license applicants.

Throughout the year, the FDA also issued other guidance related to drugs and biologics research, largely related to addressing the COVID-19 pandemic, as discussed in the above section on COVID-19 and research.

Effective March 27, 2020, the HHS Secretary declared circumstances were appropriate to authorize the emergency use of drugs and biologics in response to COVID-19 in accordance with Section 564 of the Food, Drug & Cosmetic Act. Throughout the year, the FDA has published a list of emergency use drugs and biologics approved in response to the COVID-19 pandemic. The FDA has also published a list of novel drugs that have been approved in 2020.

F. Federal Grants Developments

Authors: Clint Hermes, Whitney Mosey, Elaine Naughton, and Angelique Salib, Bass, Berry & Sims PLC

Clinical research funded by the federal government is subject government regulation, contracts, and policies. The misuse of grant funds or improper accounting of grant funds can lead to liability under the False Claims Act ("FCA"). Below are some of the major developments related to the regulation of federally-funded research in 2020, including notable FCA settlements.

It was announced in January 2020 by the Department of Justice ("DOJ") that the University of North Carolina at Chapel Hill ("UNC") agreed to pay over $4.5 million in January 2020 to resolve an overpayment that resulted from errors in grant accounting procedures spanning from 2007-2011 and again from 2014-2017. UNC discovered errors in 2011 and subsequently made written self-disclosures relating to grant closeout procedures. UNC made additional self-disclosures relating to accounting issues after discovering errors with new financial software caused UNC to retain excess grant funds,

to charge salary costs to grant awards after the award term had ended, and to retain excess cash.

The NIH released its "Guidance for NIH-Funded Clinical Trials and Human Subjects Studies Affected by COVID-19" on March 16, 2020, as described above.

The DOJ announced in April 2020 that Harvard University agreed to pay over $1.3 million to resolve allegations that the T.H. Chan School of Public Health overcharged grants funded by NIH and HRSA. The settlement results from a 2016 self-disclosure. A professor and her team overstated the time and effort spent providing statistical analysis support for other professors on grant-related research, including evenly distributing the team's time across multiple grants, instead of accurately accounting for the time spent on particular grants. The alleged conduct occurred from at least 2009 to 2014. The DOJ noted that the school did not conduct a timely review of the professor's records despite repeated concerns over timekeeping practices.

In September 2020, the DOJ announced that the Scripps Research Institute ("Scripps") agreed to a $10 million settlement to resolve allegations under the FCA that Scripps improperly charged NIH-funded research grants for time spent by researchers on non-grant related activities, including writing new grant applications, teaching, and other administrative tasks. The settlement arose from a whistleblower lawsuit brought by a former Scripps employee.

The NIH released its "Final NIH Policy for Data Management and Sharing" on October 29, 2020, which intends to promote the management and sharing of scientific data generated from NIH-funded or conducted research. The policy requires submission of Data Management and Sharing Plans for approval by the applicable NIH Institute, Center, or Office ("ICO"). The applicable NIH-ICO will be monitoring compliance with approved plans. Non-compliance may be taken into account for future funding decisions. Grant recipients have time to familiarize themselves with their obligations under the policy, which becomes effective January 25, 2023.

G. International Research

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Many U.S. healthcare and research institutions participate in research that takes place in whole or in part overseas. And as in the U.S., regulatory efforts overseas relating to research in 2020 (other than data protection laws, as described elsewhere) have been aimed at the pandemic.

These have included regulatory guidance in most major economies in line with the FDA guidance on clinical trials described above, including from the European Medicines Agency (Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic), the UK's Medicines and Healthcare products Regulatory

Agency (Managing clinical trials during Coronavirus), and Japan's Pharmaceuticals and Medical Devices Agency.

In addition, while the substantial majority of clinical trials globally still take place in countries classified by the World Bank as high income, a significant and growing number are being conducted in Latin America, Eastern Europe, the Middle East, Brazil, China, India, and South Africa. Several low- and middle income countries, including China, India, South Africa, Kenya, Brazil, Mexico, and Peru, have issued guidance or directives pertaining to clinical research during the pandemic. These guidance documents often mirror the content of similar documents from the FDA, the European Medicines Agency, and the UK's Medicines and Healthcare Products Regulatory Agency. Typically, they urge those conducting trials to take steps to protect participants; allow flexible amendments to protocols for participant safety, remote study visits and monitoring; and in some cases, explicitly prioritize COVID-19 trials.

H. Privacy Law and Regulation and Research

Authors: David Peloquin, Cara Dermody, and John Giampa, Ropes & Gray LLP

1. CCPA Amendment

The California Consumer Privacy Act ("CCPA") is a broad privacy law that took effect on January 1, 2020 and applies to many businesses that process the personal information of California residents, including entities located both inside and outside of California. In September 2020, California's legislature amended the CCPA to exclude from the law many research activities. The statement of purpose for the amendment declared that this amendment would mitigate the harm caused by the CCPA to certain health-related information and research by "preserving access to information needed to conduct important health-related research." The amendment added an exception to the application of CCPA for information collected or disclosed in research that is conducted in accordance with HIPAA, the Common Rule, Good Clinical Practice guidelines or the human subjects research requirements of the FDA. In addition, the amendment clarified that patient information that has been de-identified to the standard set forth in the HIPAA Privacy Rule will also be considered de-identified for purposes of CCPA. These changes bring the CCPA into greater harmony with other areas of research regulation and allow for those involved in clinical research to interact with personal information with greater certainty about the extent of their obligations. These portions of the amendment were made effective immediately, in accordance with the purpose statement noted above.

The amendment also includes new obligations for businesses that process health data, which were effective upon passage. The amendment introduces a new requirement that businesses selling or disclosing de-identified health information must notify consumers of such sale or disclosure in their privacy policies and specify whether the information was de-identified in accordance with the HIPAA safe harbor or the expert determination method of de-identification. Re-identification of personal information is prohibited, except for certain enumerated purposes, including for research conducted in accordance with the Common Rule. Further, effective January 1, 2021, the amendment requires that

contracts for sale or license of de-identified patient information include certain provisions, such as a statement that re-identification is forbidden and a requirement that further disclosure to a third party is prohibited except where the third party is bound by equally strict or stricter restrictions and conditions. California voters recently voted to approve Proposition 24, which will further change the privacy protection regime in the state by implementing the California Privacy Rights Act of 2020, an expansion of consumer data privacy laws, set to take effect January 1, 2023.

2. New York's SHIELD Act

New York's SHIELD Act took effect in March 2020. This law heightens the data and security breach notification requirements for entities that maintain the personal and private information of New York residents, regardless of whether the entity conducts business in New York. Entities that are in compliance with HIPAA will also be deemed to be in compliance with the SHIELD Act, which will mean that many clinical researchers and research institutions will not need to take substantial additional steps to come into compliance with the SHIELD Act. However, research universities and independent research institutes that are not HIPAA covered entities may have new obligations to safeguard personal information under this law.

3. GDPR

The General Data Protection Regulation (the "GDPR") is a far-reaching privacy regulation of the European Union that imposes restrictions and obligations on, among other types of entities, those seeking to transfer certain types of personal data from the European Economic Area (the 27 member states of the European Union plus Iceland, Liechtenstein and Norway) to the United States (and other third countries). One mechanism that was developed to enable cross-border transfers of personal data was the EU-U.S. Privacy Shield Framework ("Privacy Shield"), which allowed participant entities which met certain privacy requirements and self-certified to the Privacy Shield with the U.S. Department of Commerce to engage in cross-border transfer of personal data.

In July 2020, the Court of Justice of the European Union ("CJEU") invalidated the Privacy Shield framework in a decision commonly referred to as the Schrems II decision. This decision eliminated the Privacy Shield as a mechanism to legitimize the cross border transfer of personal data. The CJEU ruled that the Privacy Shield did not provide adequate protections to persons located in the European Union, particularly with respect to the national security surveillance laws and programs of the United States.

Pursuant to the CJEU's opinion in the Schrems II decision, companies may continue to rely on the other data transfer mechanisms set out in GDPR. These include the "standard contractual clauses," which are standard form contracts promulgated by the European Commission that are designed to offer sufficient safeguards for data transfers to comply with GDPR, and alternative bases such as obtaining the explicit consent of the individual to whom the information pertains. Notably, the Schrems II decision required that

supplementary measures be taken in some cases, such as when relying on standard contractual clauses, to ensure compliance with the level of protection of data required by EU law in a particular third country. The European Data Protection Board ("EDPB") issued guidance (1, 2) setting out recommendations on supplementary measures that may be required to legally transfer data outside of the EEA, including identifying all transfers, verifying transfer tools, assessing laws and practices in the country to which data are being transferred, adopting supplementary measures to ensure data are protected at the required level of "essential equivalence," and taking any formal procedural steps required by the transfer tool being used.

The Schrems II decision and accompanying EDPB guidance have had significant impacts on research taking place in Europe in collaboration with U.S.-based researchers and sponsors. Companies involved in trans-Atlantic data flows have had to re-evaluate their data sharing practices in light of the EDPB guidance, which has stalled certain multi-national research projects. The U.S. federal government is examining this issue and considering solutions, including in a December 2020 hearing on the invalidation of the EU-U.S. Privacy Shield and the future of transatlantic data flows.

4. Certificates of Confidentiality

Certificates of confidentiality ("CoCs") are issued to help protect the privacy of human research subjects in certain sensitive contexts (*e.g.*, research on the effects of alcohol and psychoactive drugs) by preventing researchers from being compelled to disclose identifiable, sensitive information ("ISI") about participants. Although the initial CoC rules were intended to shield researchers from being compelled through judicial process to disclose ISI about research subjects, the scope of CoCs was significantly expanded by the 21st Century Cures Act and now includes an affirmative prohibition on disclosure of ISI by researchers absent a legal basis under law for the disclosure. The 21st Century Cures Act also expanded researchers' ability to obtain a CoC by making the issuance of a CoC mandatory for investigators engaged in federally funded research involving ISI. Guidance issued by the NIH in 2017 eliminated the need for NIH-funded researchers to request the CoC – instead, CoCs were issued automatically for research funded wholly or in part by the NIH that collects or uses ISI. Under the current rules, several components of HHS, including FDA, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, NIH, the Indian Health Service and the Substance Abuse and Mental Health Services Administration, issue mandatory CoCs to federally funded researchers and have the discretion to issue CoCs for non-federally funded researchers.

In November 2020, the FDA released guidance on the process for non-federally funded researchers to seek CoCs from FDA. This guidance largely centers on what information should be submitted in connection with a CoC request, including information about the institution, researcher and nature of the research. FDA also suggests that the request should include certain written assurances about complying with requirements to protect confidentiality and acknowledgement of the scope of the CoC protections. The guidance indicates that FDA expects to issue CoCs in response to most discretionary requests that

are in compliance with the statutory requirements. Non-federally funded researchers should ensure that requests for discretionary CoCs are made in a way that aligns with this recent guidance.

5. Telemedicine Enforcement Discretion and Research

The Office for Civil Rights within the U.S. Department of Health and Human Services ("OCR"), which is responsible for enforcement of the HIPAA Privacy, Security and Breach Notification Rules, issued guidance in response to the COVID-19 pandemic indicating that it will exercise enforcement discretion with respect to enforcement of certain telehealth activities which are not in compliance with HIPAA. Covered health care providers may use applications such as Zoom or Skype to provide telehealth services in good faith without fear of enforcement from OCR, even if the services being provided do not relate specifically to COVID-19.

This guidance has had important implications in the research context, as many research-related activities, such as clinical trial subject study visits, have been conducted via telehealth instead of in person during the pandemic. FDA has issued guidance on best practices for clinical trials using telemedicine, including implementing training for investigators or study personnel, creating procedures to maintain participant privacy, and confirming identity before beginning a virtual visit. It is expected that many clinical trials will continue a "remote" or "decentralized" model that relies heavily on telemedicine, even after the pandemic ends and thus researchers will need to monitor closely guidance from OCR and FDA regarding use of telemedicine technologies in research following the pandemic.

I. Big Data and Research

Authors: David Peloquin, Cara Dermody, and John Giampa, Ropes & Gray LLP

1. National COVID Cohort Collaborative

COVID-19 has continued the pre-pandemic trend of the growth of "big data" research projects. In response to the COVID-19 pandemic, the NIH launched the National COVID Cohort Collaborative ("N3C"), a centralized national data resource available to the research community to study COVID-19 and identify potential treatments. Under N3C, hospitals and health plans submit clinical, laboratory, and diagnostic data in the form of a limited data set to the NIH for inclusion in the centralized platform. Participation in N3C, and other similar initiatives, generally requires entering into data use agreements, the terms of which become more complex when institutions leverage regional data collaboratives to facilitate such participation. Lawyers must navigate the limitations of existing collaborative participation agreements and data use agreements to enable the release of important COVID-19 data to N3C, a challenge that may be addressed in future agreements by incorporating provisions that contemplate the potential for regional collaboratives to coordinate with national programs, especially during public health emergencies. Thus, N3C may assist with determining how to structure

relationships between hospitals, health plans, and regional and national collaboratives to better address future public health emergencies.

2. COVID-19 Diagnostics Evidence Accelerator

In June 2020, the FDA announced its participation in the COVID-19 Diagnostics Evidence Accelerator, a collaborative that allows for the analysis of both diagnostic and clinical data in real-time by convening experts in data aggregation and analytics to compare results and answer key question to inform the COVID-19 response. The Diagnostic Evidence Accelerator evaluates the performance of COVID-19 diagnostic tests and antibody tests, focusing on determining whether the presence of antibodies indicates future immunity, and which specific antibodies may contribute to such protection. The collaborative demonstrates the growing importance of coordination among experts in data aggregation to determine how to leverage big data to address the COVID-19 pandemic.

3. Information Blocking

Information blocking is a practice through which health care providers or other holders of electronic health information impose barriers to the access, exchange, or use of such electronic health information by another party. Pursuant to the 21st Century Cures Act, the Office of the National Coordinator (ONC) of HHS issued a series of regulations which prohibited health care providers or health IT developers from interfering with access, exchange or use of electronic health information, with certain defined exceptions. This rule had an effective date of November 2, 2020. However, an interim final rule with comment period was released in October 2020, delaying the compliance date for the information blocking rules until April 5, 2021.

Under the rule, to constitute prohibited information blocking, the interference must be known to the provider to be unreasonable and likely to interfere with access to information. One implication of these rules for the research community is that when patients have executed a HIPAA authorization permitting researchers to access their existing electronic health information held by covered entity health care providers, researchers will likely be able to invoke the information blocking rules (once effective) to require the covered entity health care provider to disclose information for research in response to the authorization. This should prove a helpful development for researchers given that authorizations have historically been seen as a "permissive" basis for disclosure of protected health information ("PHI"), and thus some health care providers have refused to disclose PHI to researchers in response to broad authorizations. Providers may impose cost-based fees on researchers or others requesting the information to compensate for the time and effort involved in transferring such information.

4. Access to Information under HIPAA Notice of Proposed Rulemaking

On December 10, 2020, OCR released a notice of proposed rulemaking that proposed changes to the HIPAA Privacy Rule to support care coordination and the delivery of

value-based care. The proposed rule would compel covered entities to adopt policies and procedures that allow for better access by individuals to their own PHI, would clarify when disclosures for care coordination and case management are permitted, and would loosen the requirements relating to the provision of a notice of privacy practices. In addition, the proposed rule would clarify the right for individuals to direct the sharing of PHI in an electronic health record used among covered entities by allowing individuals to request that covered entities share their PHI. The proposed rule permits reasonable fees in connection with the labor and expenses associated with these requests. The provision of the proposed rule clarifying the rights of individuals to direct sharing of their PHI, if ultimately adopted, could prove useful in a research setting where the transfer of PHI between covered entities regarding a research subject may be necessary.

J. Clinical Trial Registration and Data Transparency

Authors: David Peloquin, Cara Dermody, and John Giampa, Ropes & Gray LLP

1. Enforcement of ClinicalTrials.gov Submission Requirements

Under section 402(j) of the Public Health Services Act ("PHS Act") and its implementing regulations at 42 C.F.R. part 11, sponsors (or other "responsible parties") of most clinical trials must register such trials and post summary results from such trials on ClinicalTrials.gov. The website serves as a public resource for the identification and matching of trials with potential participants as well as for reviewing summary results of clinical trials. FDA and NIH have faced criticism for not enforcing these requirements. For example, a recent article in Science reported that approximately 16 percent (30 of 184) of sponsor organization with at least five trials that had reporting results due as of September 2019 never met a single reporting deadline, and those violators had failed to report any results for 67 percent of their trials. Further, the federal District Court for the Southern District of New York recently found in a case brought by two leading researchers, who argued that their research had been hindered by the lack of clinical trial information on ClinicalTrials.gov, that HHS misinterpreted the relevant sections of the Public Health Service ("PHS") Act in its implementing regulations by providing that results of certain clinical trials of non-approved products would not need to be submitted to ClinicalTrials.gov. The court found that the PHS Act applies more broadly than as described in the regulations promulgated by HHS and NIH. This decision has resulted in responsible parties needing to post results for additional trials.

In August 2020, FDA issued a guidance document (the "Guidance") describing how FDA will identify noncompliance, initiate enforcement actions, and assess civil monetary penalties ("CMPs") for noncompliance with ClinicalTrials.gov requirements. Specifically, the FDA will focus its compliance efforts on parties who fail to submit data for clinical trials of high-risk products and on those who exhibit a pattern of noncompliance. If a party is not in compliance, FDA will issue a Preliminary Notice of Noncompliance, to which the party has 30 days to take corrective action. If the party fails to take such action, FDA will issue a public Notice of Noncompliance, to which the party has an additional 30 days to address its noncompliance. The Notice of Noncompliance is posted on FDA's website and provided to NIH to be posted on

ClinicalTrials.gov. If the noncompliant party again fails to take adequate corrective action, FDA will seek CMPs.

Under the CMP proceeding process, FDA presents a formal complaint with sign-off by the FDA Office of Chief Counsel, and the responsible party may submit an answer, including any objections, to such complaint within 30 days of the date of service. Parties who file objections within those 30 days are entitled to a hearing. Such parties also may seek to settle claims for a lower penalty. If FDA and the party do not reach a settlement, the claims will be adjudicated before an administrative law judge ("ALJ"), and either party may appeal the ALJ's decision to the HHS Departmental Appeals Board ("DAB"). The respondent may appeal adverse DAB decisions to the U.S. Court of Appeals for the District of Columbia or another circuit court where the respondent resides or does business.

The Guidance provides that FDA will consider "the nature, circumstances, extent, and gravity" of the violation, the violator's compliance history and ability to pay, its degree of culpability, and "such other matters as justice may require." The Federal Food, Drug, and Cosmetic Act caps the CMPs at $10,000 (inflation adjusted to $12,316 for 2020) for violations adjudicated within a single proceeding or, if a responsible party fails to remedy its noncompliance within the notice period, $10,000 per day of continuing noncompliance.

2. EMA Policy 0070

The European Medicines Agency ("EMA") Policy 0070 generally requires the publication of anonymized clinical study data regarding medicinal products for human use submitted under the EMA's centralized marketing authorization procedure. In December 2018, the EMA suspended the publication of clinical data as a result of the implementation of the third phase of EMA's business continuity plan, and the publication remains suspended due to "ongoing business continuity linked to the COVID-19 pandemic." EMA has not provided a timeframe yet for when the suspension will be lifted but confirmed that it will publish clinical trial data submitted concerning the marketing authorization application of a medicine intended to prevent or treat COVID-19. This commitment is part of EMA's efforts to support global research that may help to address the COVID-19 pandemic through greater information-sharing.

K. Biorepositories and Specimen Research

Authors: David Peloquin, Cara Dermody, and John Giampa, Ropes & Gray LLP

1. State Laws on Genetic Privacy

The federal Genetic Information Nondiscrimination Act ("GINA"), passed in 2008, bans discrimination based on genetic information in the health insurance and employment settings, but does not address the life, long-term care and disability insurance context. However, many states have taken legislative steps to provide additional protection to individuals from genetic information discrimination beyond that provided by GINA.

Given the broad use of genetic information in research, the recent action by state legislatures in this area may carry important implications for clinical research.

In summer 2020, Florida passed a bill prohibiting life, disability and long-term care insurance companies from using genetic tests to make coverage and rate setting decisions. Although insurers are prohibited from using genetic information for these purposes, or soliciting applicants or covered individuals for their genetic information, individuals are still permitted to volunteer their information. Washington State is currently considering a bill, introduced earlier this year, which would require direct-to-consumer ("DTC") genetic testing companies to comply with additional consent requirements and other consumer protections, including a requirement that DTC genetic testing companies obtain informed consent consistent with the Common Rule to use identifiable data for research purposes or to transfer or disclose identifiable genetic data to third parties for research purposes. The California legislature passed a similar piece of legislation in 2020, which was vetoed by Governor Newsom in September 2020 due to concerns that the bill would inhibit the sharing of COVID-19 test results by clinical laboratories for public health purposes.

A number of other states are currently considering laws that would provide additional rights to consumers and further protections against genetic information discrimination, including Georgia, Illinois, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Caroline, Tennessee, Vermont and Virginia. This is an area that continues to evolve and that should be monitored by those engaging in genetic research on humans or human-derived specimens.

2. Banking of COVID Samples

Although there has not been a specific legal or regulatory development to note, the COVID pandemic has emphasized the need for the use of banked biospecimens for public health and research purposes. Those engaged in COVID research frequently wish to access saliva, blood and other specimens collected in the course of routine COVID testing, and many entities have been banking residual COVID testing samples for this purpose. There are several regulatory considerations that should be addressed when collecting or using these banked specimens. CDC has issued COVID-specific biospecimens handling guidelines that are intended to ensure safety for personnel involved in these activities. Those conducting research need to consider whether research conducted on banked specimens constitutes human subjects research, and if so, should assess the need to comply with the Common Rule (as recently revised), OHRP guidance and other applicable research regulations and guidance, including with respect to informed consent and identifiability of samples. If banked samples will be used in support of an FDA submission, the researchers will need to consider the applicability of the FDA's regulations on clinical investigations. Additionally, depending on the types of personal information associated with the specimens, researchers will need to consider the application of HIPAA, the Family Educational Rights and Privacy Act and other privacy laws to the research activity.