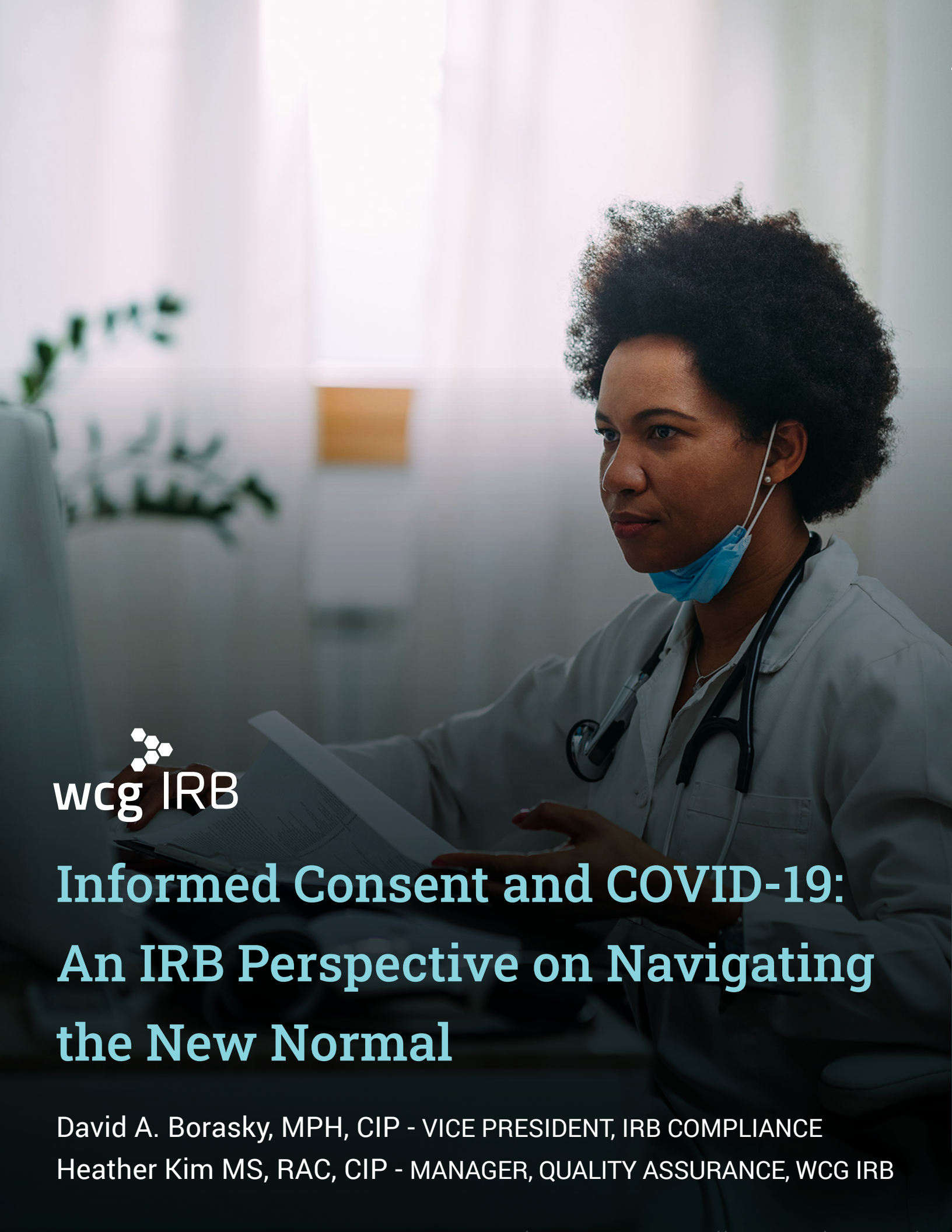

wcg IRB

Informed Consent and COVID-19: An IRB Perspective on Navigating the New Normal

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COVID-19 has completely transformed the way patients, sites, sponsors, and CROs engage in clinical research and with each other. Almost every aspect has changed, and many of those changes require IRB notification, so it's not surprising that we've received hundreds of questions from sites and sponsors.

Those questions touch on an array of issues, and those issues have changed over the course of the pandemic. A few, however, have remained constant; for example, we continue to receive questions about informed consent.

As you already know, regulations require initial consent, and they require consent to changes that could affect a participant's willingness to continue in the trial. However, the regulations don't detail exactly how.

CONVEYING INFORMATION

New information can be presented in a multitude of formats:

- It could be a *revised consent document*. Sometimes, that is the most appropriate way to go about it—for instance, when there's a significant number of changes throughout the originally approved consent form.
- In other cases, it could be an *addendum to a consent form* that narrowly focuses on the changes to a specific section, or maybe to the list of procedures that are happening.
- It could also be as simple as a *memo, or a letter*, or some other written communication sent to the participant.
- In some circumstances, it could be *oral communication* by phone or in person.
- The FDA is making its MyStudies app available to investigators as a free platform to obtain informed consent securely from participants for eligible clinical trials. It is available through both the Apple App store and the Google Play store.

All this is to say there are several completely appropriate ways to satisfy the requirement that don't involve revising the consent form with the burden of having all sites re-consent participants.

From a regulatory standpoint, remote consent is permissible as long as consent is documented. If it is not possible to document in real time, use witnesses to confirm that the patient completed the consent process. So, our advice is to document everything.

Ideally, the approach will be the one easiest for the participant. According to the Secretary's Advisory Committee on Human Research Protections (SACHRP), "When there is a need to present participants with new information, IRBs should encourage use of the least burdensome approach for the participant."

Sometimes, that approach is digital.

E-SIGNATURES AND E-CONSENT

One of the most common questions we receive is: Does 21 CFR Part 11 apply to e-consent and e-signatures? The answer is "Yes." The FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency states that "systems used to generate electronic signatures… including informed consent documents, during the COVID-19 public health emergency must comply with the requirements outlined in FDA regulations at 21 CFR part 11."

21 CFR Part 11 compliance dictates that those companies who use electronic systems for document and signature control must provide assurance that the electronic documents are authentic.

What does this mean? It means you need to have the right tools for e-consent. Many of the tools that are available for electronic signature fail to comply with Part 11. For instance, Adobe, DocuSign and similar e-signature products have both Part 11- and non-Part 11-compliant versions.

GET APPROVAL

Regardless of delivery format, any written communication intended for participants to explain study changes or new procedures requires IRB approval; ICH-GCP guidelines are quite clear about that. Moreover, based on our interpretation of FDA regulations, we believe that changing the method from a paper consent to electronic also requires IRB review.

But we also believe IRBs need to consider what the sponsor, the principal investigator or the site thinks is a compelling way to convey this information.

DOCUMENT, COMMUNICATE AND STAY NIMBLE

The COVID-19 pandemic has forced everyone involved in the clinical trial enterprise to be more agile, including IRBs and regulators. In fact, regulators, including the US FDA and the Office of Human Research Protections (OHRP), have been very responsive. For example, the FDA quickly set up a dedicated email address for COVID-19 questions: Clinicaltrialconduct-COVID19@fda.hhs.gov.

Likewise, IRBs must allow sites to be nimble. The philosophy of the WCG IRBs—and, we hope, the philosophy of IRBs everywhere—is that the regulations provide us with a great deal of latitude and now is not a time for IRBs to be afraid to use it. No IRB should be a roadblock to making changes that are scientifically valid, ethically appropriate and maximize safety.

Sometimes a site or sponsor may need to make an immediate change for the best interest of those involved in the research. Modifications made without IRB approval must be submitted as soon as possible—ideally, within five days. Of course, the pandemic doesn't give carte blanche to implementing changes without IRB approval.

We're all playing this by ear, in many ways. So, I would say be vigilant, continue to communicate, document everything, and when in doubt—again—reach out to your IRB and even to the FDA and say, "What do we need to be doing here that we haven't thought of?" It is better to ask too many questions than too few.

Links to frequently asked questions related to research and COVID-19, as well as links to the previously discussed OHRP and FDA guidance, are available here.

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