



# MEDICAL ETHICS ADVISOR

YOUR PRACTICAL GUIDE TO ETHICS DECISION-MAKING  
AND INSTITUTIONAL REVIEW BOARD MANAGEMENT

MARCH 2022

Vol. 38, No. 3; p. 33-48

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## Citizen Science Projects Surging, But Often Lack IRB Ethical Oversight

IRBs are responsible for ethical oversight of clinical trials, but this generally does not apply to “citizen science,” which involves the participation of lay individuals in scientific studies. “Citizen science is really just a different approach to research, where we are engaging participants in, typically, pretty meaningful ways. That raises issues that traditional research frameworks may not adequately address,” says **Christi Guerrini**, JD, MPH, assistant professor in the Center for Medical Ethics and Health Policy at Baylor College of Medicine.

More than 60 ethical issues related to citizen science were identified by stakeholders who participated in a 2017 workshop funded by the National Science Foundation.<sup>1</sup> “Many ethical issues were identified that perhaps are unique to citizen science, or are well-known in research, but are presented differently in the citizen science context,” says Guerrini, a participant in the workshop.

However, it was unclear which of those ethical issues should be prioritized for further study and problem-solving. “There are limited resources for citizen science leaders and practitioners to start

tackling issues. It’s not quite clear ... what we should be focusing on first,” Guerrini says.

Guerrini and colleagues picked up where the workshop left off by prioritizing all the identified ethical issues. They surveyed 108 practitioners, participants, and scholars in citizen science on the most and least concerning ethical issues.<sup>2</sup> To make the survey manageable, participants were asked to rate just 11 of the ethical issues.

“Importantly, we only selected ethical issues that could apply to any kind of citizen science project. There are some that are very concerning to specific kinds of projects, but are not at all relevant to others,” Guerrini explains.

For example, bodily autonomy is relevant specifically to human health research, so it was not included in the survey. Based on the responses, researchers classified participants into two groups:

**“Power to the People.”** This group was concerned mostly about issues involving power imbalances between participants and project leaders, exploitation of participants, and lack of diversity among participants.

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**Financial Disclosure:** None of the planners or authors for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

*Medical Ethics Advisor*®, ISSN 0886-0653, is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Medical Ethics Advisor*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.

GST Registration Number: R128870672.

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**“Show me the Data.”** This group was focused mainly on data-related ethical issues — most commonly, quality of data and failure to share data.

Overall, four ethical issues were identified as most concerning: failure to return results, exploitation of participants, poor quality data, and power imbalance. “One takeaway for researchers engaged in citizen science is to pay attention to issues of power and exploitation, and to think about what processes they might use to get ahead of those concerns,” Guerrini suggests.

Whether citizen science projects receive IRB oversight depends on whether they are covered by the Common Rule requirements for human subjects research. While much citizen science research is not subject to IRB review, some projects are conducted in conjunction with university or nonprofit staff who are subject to the Common Rule requirements. “They could also, if they have the budget, opt for review with a private IRB,” adds **Lisa M. Rasmussen**, PhD, organizer of the 2017 workshop.

Guerrini would like IRBs to pay attention to the fact citizen science projects are styled differently from traditional study protocols. Mainly, this comes up in terms of the involvement and engagement of citizen scientists. “Some citizen science might involve ‘traditional’ research subjects, in the sense that they are subject to an intervention. Some might not,” Guerrini says.

Adding to the complexity, in some projects, citizen scientists are both collecting and analyzing data. When individuals are actually handling the work of researchers, they are not really “human subjects” as defined by IRBs. “It raises a number of questions about protections and

risks and benefits,” Guerrini says. For IRBs, the challenge is to ask the right questions. “IRBs absolutely need to do their work in terms of upholding regulatory requirements. The work of IRBs still needs to be conducted very rigorously,” Guerrini says. “I would hope that IRBs [remain] willing to ask more questions in order to better understand the citizen science projects.”

When it comes to citizen science, how is “human subject” defined? If someone takes a photo of a bird and uploads it, that is not what researchers typically would consider a “human subject.”

“But if their location information is included in the uploaded photo — particularly if, for example, they took a photo at their home — that seems to fall under the purview of the Common Rule,” notes Rasmussen, professor of philosophy at UNC Charlotte and co-author of a paper on ethics and citizen science.<sup>3</sup>

Another issue is IRBs usually take an equality approach with participant compensation (i.e., equal pay for equal work). “But for a variety of reasons in citizen science, an equity approach ... might be more ethical,” Rasmussen says.

IRBs often are highly focused on protecting autonomy of human research subjects. This might not apply to citizen science research. “Maybe protecting citizen scientists from harm of privacy breach, a typical IRB worry, is a non-issue,” Rasmussen says.

On the other hand, an IRB might not reflect at all about whether citizen scientists are treated as equals because that is not their mandate. “In other words, the ethical worries of IRBs and citizen science may not always match up,” Rasmussen says.

IRBs must understand citizen science better in many cases,

according to Rasmussen. “The strict letter of the regulations may not be keeping up with the moral principles actually operating in these areas,” she says. “IRBs should not be so dedicated to regulatory compliance that they fail to notice ethical issues in citizen science.”

IRB members must consider all these issues, since IRBs will be seeing

more citizen science projects. “This style of research has become very popular,” Guerrini says. “There is no question that citizen science is not a fad. It is here to stay.” ■

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# Are Neurotechnology Tools Designed Ethically? Public Is Skeptical

Designing new neurotechnology tools poses many ethical challenges — agency, privacy, equality, normality, and justice among them. “Ethics in the development of neurotech is a core priority for us,” says **Scott Ransom**, PhD, director of industry and innovation at the University of Washington Center for Neurotechnology.

At the center, neuroethicists are embedded into the labs alongside neurotechnology researchers. To Ransom, it was clear industry members highly valued ethics. Industry members also tended to believe society would embrace new technologies with confidence because of assurances that the industry developers had infused ethics into the design. Here, Ransom saw somewhat of a disconnect. “In talking with regulators and laypeople, it was clear that they did not share that assumption,” Ransom explains.

People did not see medical device companies as nefarious or operating with ill intent; rather, many viewed the companies as revenue-generating entities that would not necessarily prioritize ethics in their design choices. Ransom and colleagues wanted to quantify this gap in attitudes between what the neural device industry thought about how seriously

they took ethics and what the public thought about it. They surveyed 66 industry professionals and 1,088 members of the public.<sup>1</sup>

The industry professionals were highly confident that neural devices would be designed in a way that addressed ethical issues. The public was not as confident.

“We confirmed there was a gap in priorities related to privacy and consent between members of industry and the general public,” Ransom reports.

Both groups agreed there was a need for guiding ethical principles in development of neurotechnology. The groups differed somewhat in terms of confidence in the industry to incorporate ethical concerns in the design process. The public was much more likely to believe consent should be required for companies to collect brain data vs. industry responders. “This gap between what industry felt their level of neuroethics investment was and what the public in general saw it to be could have impacts to the adoption of tech,” Ransom says.

People might not trust newly developed devices if they lack confidence in ethical design. “These days, the definition of who is a medical device ‘customer’ is more complicated

than ever,” Ransom adds. “Consumer choice extends to doctors. They often are the ones making the purchase decision for the patient based on patient need.”

Hospitals and third-party payors that purchase these devices want to know they can trust how data from devices are used. “Lack of confidence by all of these ‘consumers’ hinders market adoption and, ultimately, reduces the number of people the devices help,” Ransom says.

For industry members, the study’s findings show they cannot just assume people trust them to design devices ethically. “There’s a need to be more intentional about how they incorporate neuroethics in the design process,” Ransom says.

Marketing campaigns and advertisements are one way industry can spread the message. “But even more fundamental is incorporating patient and end user feedback in the design process,” Ransom says.

Regularly meeting with patients, physicians, and regulators and developing a deep understanding of their needs and concerns is the best path forward. The Ransom and colleagues analysis revealed evidence indicating industry members respond to public opinion. Industry

professionals prioritized user privacy beginning in 2018. Ransom and colleagues attributed this to a highly publicized scandal involving Facebook and Cambridge Analytica.<sup>2</sup>

“The findings have important implications for industry professionals tasked with designing and disseminating new neural devices,” Ransom argues.

For patients, physicians, and regulators to fully adopt new

neurotechnology devices, it must be clear that neuroethical considerations were a part of the design and development process. Also, patient concerns must be addressed in the design process.

“It’s not enough for industry to do this internally,” Ransom says. “There needs to be a level of transparency — and, in fact, collaboration — with the public in setting neuroethics standards.” ■

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# Unique Ethical Issues with Research on Difficult-to-Treat Depression

Researchers face some unique ethical challenges with study protocols regarding treatment-resistant depression. “The field has largely been driven by the commonly held assumption that we can actually cure everybody if we just persist long enough,” says **Augustus John Rush**, MD, adjunct professor of psychiatry and behavioral sciences at Duke University School of Medicine.

Most patients with depression do improve, thanks to proper condition management. However, other patients do not return to normal function, and some may not be able to reach and sustain a depressive-free, symptom-free state. “Evidence-based medicine relies entirely on randomized, controlled trials. These are highly exclusive, aiming for high internal validity but relatively poor external generalizability,” Rush argues.

Many prospective participants with depression cannot participate in clinical trials because they do not meet the inclusion criteria.<sup>1</sup> “This means that we are often shooting from the hip without strong evidence as to what to do since these people are excluded from the randomized, controlled trials,” Rush says.

Rush was part of a consensus group that proposed the term “difficult-to-treat” depression, and offered recommendations for how it should be identified, assessed, and managed.<sup>2</sup> The group identified the challenges, obstacles, and opportunities in addressing the needs of those with difficult-to-treat depression. Their report focused on three important issues for clinical researchers:

- **How to define this group of patients, which is heterogenous.** “It might be difficult to define people with difficult-to-treat depression with enough specificity to define a clinical population for regulatory trial purposes,” Rush explains.

- **How to acquire and interpret clinically meaningful outcome metrics.** Traditional outcome metrics reflect short-term symptomatic changes. “Those metrics don’t necessarily apply to difficult-to-treat depression, since trials will likely be of longer duration,” Rush explains.

Instead, researchers can consider longer-term outcome metrics. For example, one metric to consider would be: “Of the last six months, what proportion of the time was the

patient symptom-free, only suffering mild symptoms (or moderate symptoms) or severe symptoms?”

- **How to design clinical trials to promote generalizability.** “A more careful, diligent evaluation will promote trial design with a focus on real-world patients who are often left out of participation in trials,” Rush says.

IRBs should realize trials must include patients who are quite ill to find out how to help this specific group. “IRBs are often so focused on internal validity that they require a curating of the sample so as to be less and less representative of real-world problems,” Rush notes.

Historically, patients with suicidal ideation are not allowed to participate in clinical trials.<sup>3</sup> “Great effort has to be made to get them through IRBs, which are guarding the institution’s reputation often at the cost of diverting research efforts,” Rush reports.

The fact remains researchers simply cannot study treatments for suicidal patients unless they observe suicidal patients. “If suicidal patients are included in clinical trials, some of those people will, in fact, attempt suicide,” Rush says.

This may make IRBs reluctant to approve a study protocol that includes suicidal patients.

“The issue is not whether suicidal patients are at risk for committing suicide, but rather whether the treatment study puts them at greater risk than ordinarily encountered,” Rush says. ■

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# Researchers Encounter Challenges with Study Development Protocols

Study protocols might be noncompliant with IRB requirements, which means several rounds of reviews before the research can proceed. “We wanted to address the issue of inconsistent compliance with research protocol requirements in order to reduce delays,” says **Alison Oliveto**, PhD, vice chair for research in the department of psychiatry and behavioral sciences at the University of Arkansas for Medical Sciences.

The institution implemented an online protocol development tool with the hope of reducing delays in IRB approval.<sup>1</sup> Oliveto and colleagues examined whether the tool provided helpful guidance for investigators and whether it led to shorter times to IRB approvals. They surveyed 23 study investigators; this small sample hindered the work to some extent. It was unclear whether this small sample was because few investigators were developing protocols at the time or whether there was just a general lack of interest. “Also, the tool itself had more quirks than anticipated that were not apparent. This made the tool less intuitive and led to lost work that frustrated users,” Oliveto laments.

Oliveto and colleagues intended to collect follow-up data on the tool’s effectiveness. It turned out this was not possible. Not one protocol

was submitted using the template the tool generated. Participants gave various reasons for not using the tool. For some, the issue was they were familiar with the existing protocol development templates at the institution and did not want to switch. Others did try the tool, but they struggled to save their work, and gave up. “One of the issues was that the online tool was not integrated into the institution’s existing templates,” Oliveto says.

Thus, a completed protocol had to be saved, downloaded, and then uploaded into the IRB submission system. The online tool has been discontinued, at least for now. Oliveto and colleagues remain open to the possibility of integrating protocol development tools into existing institutional templates as a possible way to expand use in the future. “Locally developed templates, when used, seem to help enhance protocol compliance, although the guidance in the template is not always followed,” Oliveto says.

Online protocol development tools that require completion of necessary protocol sections may help enhance protocol compliance. “However, these tools likely need to be customized to the institution and integrated within ongoing IRB processes in order to be more feasible and

acceptable to investigators,” Oliveto says.

Delays in IRB approval happen for many reasons. “Often, study teams misclassify their study submissions or misunderstand what types of studies qualify for expedited IRB review,” says **Edward Kuczynski**, director of the human research protection program at the University of California, San Francisco (UCSF). Some common examples of issues that cause delays:

- Any study involving exposure to ionizing radiation cannot be considered minimal risk, although investigators often assume a simple chest X-ray represents no more than minimal risk.

- Studies involving the use of an assay are device studies and must be evaluated by full committee to make a risk determination. However, many study teams overlook this requirement.

- There are minimal risk limits on volume and frequency of blood draws for research, especially for children. These limits often are exceeded in the original submissions and must be modified before study approval.

“Any proposed procedures that are considered greater-than-minimal-risk will require full IRB committee review and inclusion of additional supporting material,” Kuczynski notes.

There may be additional ancillary committee reviews required (e.g., radiation safety if research X-rays are proposed).

“These types of errors lead to returns for added details and delay the time to approval,” Kuczynski says.

Investigators can use consent form templates that identify required language for compliance with federal, state, and university policy. “Too often, investigators omit such language, resulting in delay of approval,” Kuczynski says.

The IRB prevents delays in a few ways. For example, study investigators are encouraged to collaborate with more experienced colleagues in their department or division. “This can improve the quality of initial submissions and help with identifying required elements,” Kuczynski says.

Elsewhere, UCSF provides extensive guidance on its IRB website to

help study teams identify required components of a protocol. Also, UCSF hosts periodic training “boot camps” and webinars. The IRB education and training coordinator conducts these trainings as part of a more comprehensive training program.

“It’s geared toward clinical research coordinators, but it’s open to all, and many individual principal investigators attend,” Kuczynski reports.

Topics start with the basics — what constitutes human subjects research, what research may be exempt from IRB review, and what constitutes minimal risk research. The training progresses to more complex issues, such as how investigators should determine risk to participants, protect privacy and confidentiality, and share data and biospecimens.

The IRB has used commercial protocol-building tools, but in a limited way. “The tools may be useful

if they can be customized to address the local context in which IRB review occurs, including consideration of local, state, and campus policies,” Kuczynski says.

The IRB has found training videos are more effective. These illustrate how to submit a protocol using the institution’s particular software. The IRB also makes exemplary applications available as models. “In the past, we considered licensing a commercial tool but found it to be inadequate to our particular needs,” Kuczynski says. “We think our training materials are more beneficial as they are targeted to our particular needs.” ■

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## IRBs Determine Acceptable Risk for Pediatric Studies

There is ongoing, significant debate about the ethics of exposing minors to research risks to benefit others.<sup>1</sup> “Many people in research ethics have written on this and offered their view. But we were not aware of any attempt to find out what a representative sample of the public thinks,” says **David Wendler**, MA, PhD, head of the section on research ethics at the NIH Clinical Center.

“Net-risk” research involves interventions that do not offer participants a potential for clinical benefit that justifies the risks and burdens they face. “Some people argue that exposing children to risks for the benefits of others is unethical,” Wendler says.

Wendler and colleagues wanted to learn more about these attitudes, including what might constitute acceptable risks and how the social value of research affects opinions on risk. A total of 1,658 U.S. adults were given one of four hypothetical scenarios, describing procedures with varying levels of risk and social value.<sup>2</sup>

Overall, 84.5% of respondents said it can be appropriate to expose children to risks if the study might benefit others. Only 15.5% said it was never appropriate. Most respondents (60.9%) said it was acceptable to expose children to somewhat higher risks if the study offers greater benefits, such as a possible cure for cancer. Generally, 91% approved of pediatric research

participants submitting to blood draws. About 69% approved of participants undergoing a bone marrow biopsy.

However, respondents would be less inclined to enroll their own children in clinical trials. About half of respondents supported clinical trials posing more serious risks (including a 1% chance of death in children with short life expectancies) if the study could lead to treatments that would extend life for future patients. Still, only one-quarter said they would be willing to enroll their own child in that hypothetical study.

Notably, the proportion of participants who agreed a procedure was acceptable expanded as the social value of the study increased.

“There was very strong support for net-risk pediatric research and willingness to accept somewhat higher risks than are typically regarded as acceptable,” Wendler notes.

IRBs may be disinclined to approve study protocols based on the mistaken belief there is little public support for net-risk pediatric research. “We don’t know for sure, but I suspect they are mostly allowing very low-risk studies and not approving study protocols when the risks are higher,” Wendler offers.

In light of this, researchers are going to show IRBs data on the risks of the interventions in question. “Don’t just claim a procedure is minimal risk. Provide data to show that it is,” Wendler urges.

To demonstrate the study’s social value, researchers could explain how the approach under investigation could help address an important health condition. “IRBs should be aware that the vast majority of the U.S. public supports net-risk pediatric research, provided it has

the potential to collect data that have social value and the risks are not excessive,” Wendler says. ■

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# Clinicians, Researchers Need New Framework for Ethical Management of Sickle Cell Disease

A psychologist frequently saw patients with sickle cell disease expressing confusion and frustration about changes to their treatment plan caused by greater restrictions on opioid medications. After witnessing a conversation between a patient and the medical team, **Siddika Mulchan**, PsyD, became moved to explore interventions to address this important issue.

“Challenges in pediatric sickle cell disease pain management abound, both in the clinical setting and in the context of research,” says Mulchan, a pediatric hematology/oncology psychologist at the Center for Cancer & Blood Disorders at Connecticut Children’s. “Patients with sickle cell disease remain an understudied population.”

In a recent analysis, the authors discovered federal funding was greater per person with cystic fibrosis vs. sickle cell disease, and significantly more research articles and drug approvals were found for cystic fibrosis vs. sickle cell disease.<sup>1</sup> “Additional challenges related to sickle cell disease pain management,

in the context of research, include appropriate assessment of sickle cell disease pain,” Mulchan says.

Mulchan and colleagues found implicit bias, health-related stigma, and potential neurocognitive impairment present challenges in ethical decision-making for youth with sickle cell disease.<sup>2</sup> “There are misperceptions of patients as drug-seeking, concerns about balancing treatment side effects with achieving adequate pain relief, medical mistrust, and poor adherence to treatment recommendations,” Mulchan reports.

To address these issues, Mulchan and colleagues developed an Integrated Ethical Framework for Pain Management. The goal is to facilitate ethical decision-making and promote health equity. “Research has documented a long-standing history of ethical injustices among the sickle cell disease population, including significant health disparities in disease outcomes, research funding, and quality of life in comparison to other chronic conditions,” Mulchan notes. “These inequities have been tied to sickle cell disease being characterized

as ‘Black disease,’ and evidence of racial disparities in healthcare are salient to patients with sickle cell disease.”

The tool characterizes pain as its own distinct problem, deserving of appropriate treatment. “Pain in sickle cell disease is often viewed as a symptom of the disease or a medical complication,” Mulchan explains.

The tool proposes healthcare providers should use the patient’s subjective report of their pain experience as data for informing treatment recommendations. “Often, the subjectivity of pain is a point of contention in pain assessment, particularly when physiological data do not support a patient’s report of pain,” Mulchan notes.

The new model posits it is the responsibility of healthcare providers to alleviate patients’ suffering caused by pain, regardless of the cause. “This collaborative and empathic approach appeared to be well-suited for patients and families with sickle cell disease, who commonly report poor patient-provider communication and relationships,” Mulchan says. ■

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challenges for pediatric sickle cell pain management in the context of the opioid epidemic. *Clin J Pain* 2021;38:88-94.

# Children Undergoing Stem Cell Transplant Lack Palliative Care

In caring for children undergoing stem cell transplantation, **Griffin Collins**, MD, often sees a clear need for palliative care.

“Stem cell transplant is a very high-risk procedure. The process is incredibly hard. The patients suffer a lot, and they’ve already suffered a lot,” says Collins, a pediatric hematologist-oncologist at UCSF Benioff Children’s Hospital Oakland.

Yet relatively few patients receive early palliative care; of those who do, many never receive comprehensive palliative care.<sup>1</sup>

“Patients and families coming to stem cell transplant are holding on to both a hope for cure and worries about suffering and treatment-related complications,” Collins explains. “The heart of what we do as palliative care providers is recognizing and managing suffering in all of its forms.”

Collins and colleagues surveyed members of the stem cell transplant team at UCSF Benioff Children’s Hospital to find out how they perceived palliative care.<sup>2</sup> Participants identified two important themes.

First, team members expressed a favorable view of the palliative care team. These members had long suspected there were so few consults because the stem cell transplant team failed to recognize the extent of suffering patients endured, or because the transplant team believed they carried the same skill set as

palliative care specialists. In fact, says Collins, “there was willingness and even eagerness from the majority of participants across disciplines to increase palliative care integration in stem cell transplant.”

Second, participants believed the palliative care team had insufficient resources to care for the many stem cell transplant patients. It turned

PALLIATIVE CARE TEAMS CAN SHORTEN LENGTH OF STAY, PREVENT READMISSIONS, IMPROVE PATIENT SATISFACTION, LOWER COSTS, AND REDUCE BURNOUT RATES.

out the stem cell transplant team was reluctant to request consults routinely from a service they saw as overloaded. “A major ethical implication is the distribution of palliative care resources,” Collins says.

Pediatric palliative care teams are limited in many medical centers. If

stem cell transplant programs were to suddenly start asking for palliative care consults, then palliative care would be stretched even thinner.

The answer, says Collins, is for institutions to invest in additional palliative care resources. “This is something ethicists can advocate for,” he says.

One obstacle is palliative care teams do not directly generate significant revenue. Thus, the challenge is to argue for more palliative care based on other arguments.

Collins says hospital leaders must understand “palliative care teams provide intangible benefits for patients and staff: improved patient satisfaction, reduced burnout, and reduced healthcare costs through reductions in average length of stay and readmissions.” ■

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# Much Remains for IRBs to Learn About Performance Measurement

Concerns over the performance of IRBs and the need for measuring their quality are well established.<sup>1</sup> “However, compared to performance measurements in healthcare, which has a long and successful history, performance measurements in IRB is still in its infancy,” says **Min-Fu Tsan**, MD, PhD.

Tsan authored a recent review of the performance measurement data literature on IRBs.<sup>2</sup> To measure IRB quality, it is necessary to first determine what it means — in other words, what specific elements constitute a high-quality IRB.

“Unfortunately, the IRB community has not been able to agree on a definition for IRB quality,” says Tsan, senior research scientist at McGuire Research Institute in Richmond, VA.

Standardized measures are lacking to assess and improve the quality and performance of IRBs. “Unlike the healthcare system, where there are thousands of standardized performance measures available at the National Quality Measures Clearinghouse to choose from, there

is none for measuring the quality and performance of IRBs,” Tsan asserts.

One school of thought holds that IRB quality should be judged by how well IRBs protect human subjects participating in research. Others contend IRB quality should be judged by the integrity of their reviews or by how consistently boards make decisions.<sup>3,4</sup> “However, IRB oversight alone is insufficient in protecting human subjects, and we don’t know how to measure human subjects protections, the quality of IRB reviews, or IRB decisions,” Tsan says.

Tsan argues a more appropriate definition of IRB quality is how well the board implements the Common Rule — not just mere compliance, but how well boards put the Common Rule into effect. A review of 104 protocols approved by 20 IRBs from 10 leading academic medical centers revealed only 20% of these protocols had satisfied all eight Common Rule-required approval criteria.<sup>5</sup> For example, 21% of IRB reviews failed to address risk minimization, and 57% of reviews failed to address risk/benefit

comparison. “High-quality IRBs, so defined, will likely provide more contributions to human subjects protections, a higher quality of IRB reviews, and better IRB decisions,” Tsan says. ■

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## More Than 2,000 Consent Forms Posted Publicly

Creators of federally funded studies have been mandated to post informed consent documents on ClinicalTrials.gov ever since the revised Common Rule requirements became effective in January 2019. However, it was unclear how many or what kind of consent forms were posted — and who was posting the forms. A group of investigators set out to answer these rudimentary questions.<sup>1</sup> “We wanted to put together a baseline analysis to get a

sense of the types of sponsors that are posting consent forms, and for what types of studies the consent forms are being posted,” explains **Sarah White**, MPH, executive director of the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard.

White and colleagues analyzed data downloaded from ClinicalTrials.gov, noting the percentage of trials with a posted consent form by funder type. There were consent forms

posted for nearly 2,100 trials from 600 mostly non-industry sponsors (as of July 2021). More than half those trials did not list funding by a federal agency. Some were initiated before the form-posting requirements went into effect. “This suggests that the consent forms were probably posted voluntarily,” White suggests.

In some cases, researchers might have posted consent forms not because it was federally required, but because the IRB required them to.

“When there is a federal requirement, sometimes IRBs apply that across the board,” White notes.

White and colleagues intend to go further and assess other aspects of the posted consent forms. “But before we get into that, we thought it was probably a good idea to put data out there on who is posting the consents,” White explains.

Posted consent forms can be useful to researchers. “In the spirit of transparency, posting the consent form is terrific,” White shares.

Since consent forms are available publicly for anyone to view, it is extra motivation for investigators to be sure consent forms present information clearly.

“It’s one thing to meet the requirements in the Common Rule; it’s another to make sure participants

understand the information,” White says.

Since the consent forms are in the public forum, it is possible the documents could be analyzed — or even criticized. “Someone could go in and assess, ‘Did the investigator draft, and did the IRB approve, a consent form that is missing some of the required elements in the federal regulations?’” White offers.

Just as people have used data from ClinicalTrials.gov to learn if all researchers have reported their results, the same is true of publicly posted consent forms.

“Researchers could run a readability scan of the posted consent forms and determine that the posted consent form was written at a reading level way higher than most people can understand,” White says.

For investigators, making all the terminology comprehensible to laypeople is a persistent challenge. “For a word like ‘randomization,’ it’s hard to put terms like that into plain language,” White notes.

Researchers also could scrutinize the eligibility criteria in the study. They might notice a subgroup of the population the researchers were trying to recruit spoke a language into which the consent forms were not translated. “There’s a tremendous benefit to having the consent forms out there,” White says. “On the flip side, people can go in and criticize them.” ■

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# Chatbots Can Help Care Managers Provide Ethical Treatment

There is no way around it — health systems are facing an ongoing shortage of clinicians to meet the needs of patients who need longitudinal care management. “You can never hire enough clinicians or providers today to do outreach and connect with people,” says **Mark E. Schario**, MS, RN, FACHE, president of University Hospitals Coordinated Care Organization in Cleveland.

Also, care managers might fail to reach patients despite making tons of phone calls. “It’s very satisfying when you talk to somebody and help them. But it’s very frustrating when you can’t make a connection, especially when you are first engaging with somebody,” Schario laments.

Chatbot technology turned out to be at least a partial solution to all these problems. Patients now

receive a text message every day, or every few days, from chatbots after they are discharged from the hospital with specific chronic conditions (e.g., stroke, asthma, congestive heart failure). The chatbots ask about the patient’s weight, blood pressure, and self-care behaviors.

At first, the mere mention of chatbots sparked multiple concerns among staff. “Not all the staff were big fans of the idea,” Schario reports.

In actual practice, the situation turned out positively. The care managers ended up freed from trying to reach patients, often unsuccessfully, which led to more quality time on high-value interactions that required clinical judgment. In several cases, chatbots made all the difference in a patient’s care. “The technology provided the right assistance at the

right time to really change the course of their illness,” Schario says.

With chatbots, patients answer important questions at any time. If everything is OK, the electronic medical record documents the interaction as “green.” If the situation is concerning, it is coded as “yellow.” In that case, a care manager is alerted to follow up right away. If the chatbot is coded as “red” (or if the patient clicks on a phone icon), it immediately transfers the call to a 24-hour nurse advice line.

Previously, ED visits and readmissions were happening specifically because patients were lost to follow-up. “We are not going to be able to hire enough people to meet the demand. We really need technology to help with that,” Schario says.

At first, some staff made comments like, “No one’s going to want to talk to a machine.” That concern was unwarranted.

“We need to give the older generation credit for being tech-savvy. We have such a variety of patients who you might not think would be engaging with a chatbot, but they do,” says **Carol A. Bahner**, BSN, RN, CCM, manager of care management in Population Health at University Hospitals.

It turned out patients appreciated receiving these daily check-in texts. “An 80-year-old might not be as tech-savvy as a 20-year-old, but is certainly

comfortable emailing and texting,” Bahner says. “Society is so much more comfortable using AI than in the past. It will be the norm in the near future.”

Care managers can intervene faster, which helps morale. “If staff are not feeling they are making a difference in the patient’s clinical outcome, that can lead to burnout,” Bahner says. Previously, care managers would finally reach a patient and everything was fine, but then the patient needed help the following day when staff did not call. “In a busy day, the chatbot helps bring people to your attention who need

help,” Bahner says. The department is planning to expand the use of chatbots to include transitions of care for people moving from an acute to ambulatory environments.

“This is where people are at today. They want short, crisp interactions,” Schario says. “The possibilities of using a chatbot to assist with care are limitless.” ■

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## Chaplains Distinctly Equipped to Address Moral Injury

Ethicists are called on often to address moral injury during consults, but chaplains also are well suited for this important role. “Chaplains are distinctively equipped to explore the potential spiritual and existential dynamics frequently represented within moral injury,” says **Keith G. Meador**, MD, ThM, MPH, director for the Center for Bioethical Ethics and Society at Vanderbilt University Medical Center.


Meador noticed chaplains were engaging in the care of veterans with moral injury. To learn how chaplains in the VA Healthcare System

conceptualize and address moral injury in their work, Meador and colleagues conducted an anonymous survey of 361 chaplains.<sup>1</sup> More than 90% of chaplains indicated they encounter moral injury. “VA chaplains consistently recognize that moral injury and spiritual injury, as discerned by them, overlap but are distinct,” Meador notes.


The vast majority (90%) of respondents also agreed chaplains and mental health professionals should collaborate to provide care for moral injury. “It may offer a distinctive opportunity for collaborations

between chaplains and other providers to provide ethically responsible care that honors the particular spiritual history and commitments of veteran patients,” Meador says.


Many chaplains supported a collaborative approach to care for moral injury. This was particularly true for chaplains with advanced training in the use of evidence-based practices (through the Mental Health Integration for Chaplain Services). More than one-third of chaplains indicated they offered a moral injury group, or were planning to. Almost one-quarter of the chaplains indicated




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they collaborate with mental health to address moral injury, or were planning to.

“Systematically including chaplains as collaborators in the care of moral injury is ethically responsible in order to honor and respect the moral complexities and challenges patients face when suffering with moral injury,” Meador says.

Over the last two years, incidence of moral injury have increased among healthcare workers “because of the intensity of the pandemic and effects on healthcare staffing, burnout, and compassion fatigue,” reports the Rev. **Mike Guthrie**, director of the spiritual care volunteer services and clinical ethics at Presbyterian/St. Luke’s Medical Center in Denver.

Staffing shortages are causing nurses to question if they have compromised their professional and moral code because of higher-than-normal patient ratios. “They go home with a sense of guilt and frustration over the entire situation,” Guthrie says.

Staff had experienced moral injury over facilities’ visitor restrictions that prevented patients’ families from entering the facility. For providers, this was particularly distressing in end-of-life cases. “The moral injury of standing at the bedside in place of a loved one left many staff in distress,” Guthrie says.

When healthcare professionals experience moral injury, says Guthrie, “people experience spiritual and existential distress in the forms of self-doubt, guilt, frustration, anger, depression, and burnout.”

Collaborating with chaplains is crucial in supporting staff when they believe they have compromised their moral integrity. Guthrie argued this point in a paper on the topic.<sup>2</sup>

Chaplains are trained to work with individuals experiencing spiritual and existential distress. Chaplains could take the same approach with group debriefings of entire nursing units, such an ICU.

“This begins with educating clinicians on the signs and symptoms

of moral injury, helping leaders identify its occurrence in their staff, and referring individuals back to the chaplain,” Guthrie says.

Chaplains must also put their “boots on the ground,” says Guthrie. They should be participating in multidisciplinary rounds on critical units to witness firsthand the situations that are causing moral injury.

Using these approaches, says Guthrie, chaplains can take a lead role in addressing moral injury by “developing strategies, such as group debriefs and individual support.” ■

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# Physicians Might Discuss Medical Aid in Dying, Providing the Service Could Be Another Matter

**M**ost physicians are willing to talk with patients about medical aid in dying, but fewer are willing to serve as an attending or consultant, according to a survey of more than 500 Colorado physicians treating terminally ill patients.<sup>1</sup>

“Medical aid in dying is among the most, if not the most, contentious issue in medicine and policy today, stemming in part from the ethics of the practice,” says **Eric G. Campbell**, PhD, lead study author and director of research at the Center for Bioethics and Humanities at the University of Colorado.

Medical aid in dying is under policy consideration in many states. “We asked, ‘What can be learned from the Colorado experience to inform policymakers who are making decisions about medical aid in dying right now?’” Campbell says.

Campbell and colleagues also want policymakers to make decisions based on empirical evidence vs. relying on only advocacy and special interest groups (either for or against the practice). In Colorado, medical aid in dying was legalized in 2019. “A lot of the debate was not based on evidence and is often owned by interest groups

with deeply entrenched policy positions whose opinions on medical aid in dying may not reflect the reality of the people experiencing it,” Campbell explains.

Of physicians surveyed, 81.1% were willing to discuss medical aid in dying with patients, 88.3% were willing to refer a patient for medical aid in dying, 46.3% were willing to be a consultant, and 28.1% were willing to be an attending.

As far as actual experience with medical aid in dying, 52.3% had discussed it with a patient, 27.3% had referred a patient, 12.8% had

been a consultant, and 8.5% had been an attending. Among physicians who had been either a medical aid in dying consultant or attending, 75% reported it was time-consuming, and 46.9% reported it was ethically challenging. “The data challenged some commonly held beliefs and myths about medical aid in dying,” Campbell reports. One such belief is there is a shortage of physicians willing to provide medical aid in dying. “The data suggest that there’s a more than adequate supply of people who are willing, able, and prepared to provide medical aid in dying services,” Campbell notes.

While only 8.5% of respondents had served as a medical aid in dying attending, 28.1% said they were willing to do so. Another oft-cited concern is that patients might need to obtain medical aid in dying services from physicians who had never treated those patients. In fact, the data showed more than 80% of medical aid in dying attendings and consultants had provided care to patients seeking the service.

Medical aid in dying consultants and attendings largely reported the experience to be professionally

rewarding and emotionally fulfilling. However, all the physicians reported multiple barriers to participation. “Some physicians were concerned about being known as a medical aid in dying provider. But that was not the most prominent barrier to providing medical aid in dying,” Campbell observes.

Lack of knowledge was the most commonly reported barrier (47%). “Going forward in Colorado, providing education to physicians about medical aid in dying is clearly indicated by the data,” Campbell says. “Education needs to be unbiased and should not be colored by entrenched beliefs about the acceptability, or lack thereof, of medical aid in dying.”

Advocacy groups might underestimate the barriers physicians face, or might overestimate the extent to which providing medical aid in dying is professionally rewarding. Notably, 41% reported ethical concerns were a “moderate” or “large” barrier to participation. It remains unclear what the ethical barriers are and whether the physicians were able to resolve them.

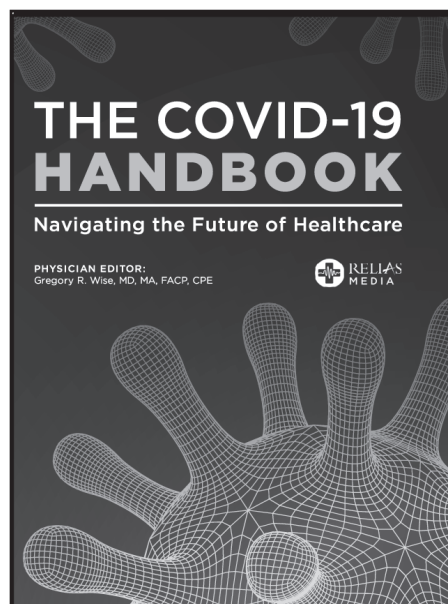
One obstacle is medical aid in dying typically occurs in the

outpatient setting, where physicians lack access to ethicists. None of the survey respondents who practiced only in the inpatient setting had ever provided medical aid in dying.

“Given that medical aid in dying almost universally occurs outside of the inpatient setting, and given that ethics consults are almost universally within the inpatient setting, there’s a need for someone to provide ethical guidance to medical aid in dying practitioners who are doing this in the community,” Campbell offers.

In states where physician aid in dying is legal, physicians are ethically obligated to inform certain patients about the option, argues **Wayne Shelton**, PhD, MSW, co-author of a paper on this topic.<sup>2</sup> Ten states and Washington, DC, have legalized physician-assisted suicide to date.<sup>3</sup> Shelton predicts that number is likely to grow in the coming years. “The whole possibility of aid in dying is evolving and is becoming more acceptable in American society,” he says.

Still, not all doctors are comfortable talking about this subject. End-of-life discussions already are fraught with difficulty,



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particularly when physicians are talking about switching from curative care to comfort care.

“Doctors, for all kinds of reasons, may shy away from having those difficult discussions with patients,” says Shelton, professor of medicine and bioethics at the Alden March Bioethics Institute at Albany Medical College.

Traditionally, the option of aid in dying has not been a part of end-of-life discussions. Some physicians fear bringing up something that is not legally permitted in their state. Even in states where the practice is legal, providers may be wary of bringing up something that may carry stigma. Still other physicians may be reluctant to bring up medical aid in dying because they believe it is morally wrong.

“But it seems that the more it becomes a viable ethical and legal option, the more doctors have an obligation to bring it up when

appropriate,” Shelton says. Even if physicians do not bring it up, the patient or a family member might do so — and providers will need to respond appropriately. Part of that response might include educating patients and family about the fact the patient can be kept comfortable even without aid in dying. Some still will request the service, and physicians need ethical responses to those requests.

“It’s hard to say that physicians have an obligation to make referrals for something they feel is wrong. It’s a matter of their own judgment and ethical perspective,” Shelton says. “But generally speaking, if someone is really insistent that they want help in dying, to guide patients in the direction to accomplish their goal in a legal way, it seems that it would be ethically appropriate to do that.”

At Albany Medical College, faculty are preparing the next generation of providers to be more adept

in managing this controversial issue before it comes up in clinical practice. “We ask medical students to think about this possibility and how they feel about helping someone with this type of service,” Shelton reports. “This will become a more common issue that physicians will have to address more head-on in the future.” ■

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## Survey: OB/GYN Residents Feel Unprepared to Care for LGBTQ+ Patients

Many OB/GYN residents feel unprepared to care for LGBTQ+ patients, according to the results of recent survey.<sup>1</sup>

Researchers surveyed 105 OB/GYN residents from accredited Illinois training programs. More than half said they felt unprepared to care for lesbian or bisexual patients. Most (76%) felt unprepared to care for transgender patients.

Participating in grand rounds focused on LGBTQ+ health and supervised clinical involvement were linked to feeling prepared to care for transgender patients. Most respondents said their programs included one to five hours a year on lesbian/bisexual and transgender healthcare. The vast majority (92%) wanted more education. Lack of experienced faculty and curricular crowding were the

two most commonly identified barriers. “While efforts are underway to improve residency training on topics pertinent to sexual and gender-diverse health, there is much work still to be done,” says **Klint Peebles, MD, FAAD**, co-chair of the American Academy of Dermatology LGBTQ/ Sexual and Gender Minority Expert Resource Group.

Of 90 dermatology residency programs, 18 included no topics relevant to sexual and gender minority patients in the curriculum, according to another study.<sup>2</sup> About half (51%) of those program administrators reported they were considering adding sexual and gender minority content. Just as in the study on OB/GYN

### COMING IN FUTURE MONTHS

- Informed consent discussions on privacy of participants’ data
- Controversy over age-based exclusions in clinical trials
- Changes make IRB decisions more consistent
- IRBs detecting scientific misconduct earlier

residents, dermatology residency program directors reported insufficient time in the curriculum schedule and lack of experienced faculty as the biggest barriers.

“Inherent within any beneficent model of healthcare is a fundamental and uncompromising respect for human rights and the right of all individuals to be treated with the utmost dignity,” says Peebles, a member of the American Medical Association Advisory Committee on LGBTQ Issues. “An ethical approach to the care of minoritized and marginalized populations, including sexual and gender minority people, necessitates a lifelong commitment to engagement and learning.”

A fundamental level of preparedness to care for LGBTQ+ patients and to understand their unique healthcare needs is essential. Peebles says residency education should include a comprehensive and inclusive approach to didactic curricula, exposure to clinical environments providing excellence in care for sexual and gender minority patients, and exposure to institutional environments that are inclusive and welcoming.

“The noble effort to ‘meet our patients where they are’ cannot be underestimated. It is one of our most powerful tools in fostering a healthy and rewarding patient-physician relationship,” Peebles says. ■

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## CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- Discuss new developments in clinical ethics and research regulation and their implications in healthcare systems for patient care, healthcare delivery, and research;
- Discuss the implications of developments in clinical ethics for patients, families, physicians, other healthcare professionals, and society;
- Review and apply principles of human subject protection in clinical trial programs, including compliance with mandated regulatory safeguards and educational requirements for human subject research.

## CME/CE QUESTIONS

### 1. Which is true regarding IRB review of citizen science research?

- a. Not all citizen science research is subject to the Common Rule requirements for human subjects research.
- b. Citizen science research projects conducted with university or nonprofit staff generally are excluded from Common Rule requirements.
- c. IRBs must ensure citizen science projects are styled similarly to traditional study protocols.
- d. More stringent requirements regarding protecting autonomy of human research subjects apply to participants in citizen science research.

### 2. Which is an ethical issue identified as concerning by stakeholders in citizen science?

- a. Disregarding high-quality data because studies have not undergone IRB review
- b. Overly lenient IRBs considering who is a “research subject”
- c. The possibility of exploitation of participants in citizen science

d. Reluctance of IRBs to review citizen science study protocols, despite the fact the protocols fall under the Common Rule

### 3. Which is true regarding attitudes toward ethics of neurotechnology?

- a. Laypeople almost universally believe medical device companies were required to prioritize ethics in design choices.
- b. Industry professionals expressed scant confidence that neural devices would be designed to address ethical issues.
- c. The public strongly disagreed that consent should be required for companies to collect brain data.
- d. Industry members believe the public would assume developers had infused ethics into device design.

### 4. Which is true regarding research on difficult-to-treat depression?

- a. Many prospective participants with depression cannot participate in clinical trials because they do not meet the inclusion criteria.

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b. Traditional outcome metrics  
reflect long-term symptomatic  
changes, but shorter-term  
metrics are needed.

c. Researchers continue  
enrolling participants with  
suicidal ideation in clinical trials  
despite unacceptable risks.  
d. IRBs should not be excluding  
patients with suicidal ideation,  
even if the study puts the  
participant at greater risk than  
ordinarily encountered.

**5. Which did researchers find  
regarding an online protocol  
development tool?**

a. The tool led to much shorter  
times to IRB approvals.  
b. Investigators found it easy to  
switch to the new tool because  
it was much simpler than  
existing protocol development  
templates.  
c. Investigators struggled  
because the online tool was not  
integrated into the institution's  
existing templates.  
d. Researchers routinely took  
shortcuts with the online tool,  
which caused delays in IRB  
approval.

**6. Which did a recent study  
reveal regarding attitudes of  
the public toward pediatric  
research?**

a. Most respondents said it was  
never appropriate to expose  
children to risks if the study  
might benefit others, even if the  
study offers benefits such as a  
possible cure for cancer.  
b. Most respondents said it  
can be appropriate to expose  
children to risks if the study  
might benefit others.  
c. Few respondents approved of  
pediatric research participants  
consenting to blood draws.

d. The proportion of  
participants who agreed that  
a procedure was acceptable  
decreased as the social value of  
the study increased.

**7. Which is recommended for  
treating patients with sickle  
cell disease?**

a. Clinicians should remember  
patients with sickle cell disease  
benefit from greater restrictions  
on opioid medications.  
b. There should be less federal  
funding and fewer drug  
approvals for cystic fibrosis vs.  
sickle cell disease.  
c. Clinicians should be focused  
only on achieving adequate  
pain relief without any  
consideration of treatment side  
effects.  
d. Healthcare providers should  
use the patient's subjective  
report of their pain experience  
as data for informing treatment  
recommendations.

**8. How did surveyed stem cell  
transplant team members  
perceive palliative care?**

a. Participants agreed  
patients undergoing stem cell  
transplantation are harmed by  
early palliative care referrals.  
b. The stem cell transplant  
team was reluctant to request  
consults from a service they  
viewed as already overloaded.  
c. Participants expressed  
unfavorable views of the  
expertise of the palliative care  
team.  
d. The transplant team saw no  
need for palliative care consults  
because the transplant team has  
the same skill set.