HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

December 2017

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

How America's Fund supports veterans

an interview with Justin Lansford

U.S. Army Veteran
America's Fund Recipient,
and Gabe's pal

See page 16

22

How to respond when ransomware catches you off guard

Theresamarie Mantese, Jordan Segal, and Paul Mantese

28

Embracing patient payment preferences, Part 2: Records and documentation requirements

Rozanne M. Andersen

35

Helping new physicians learn to improve billing and coding

Duncan Norton

39

Addressing compliance issues in reimbursement and licensing for telemedicine

Max Reiboldt

> America's Fund is by far the greatest wounded veteran-based nonprofit out there...they're also one of (if not the most) efficient—97 cents on the dollar goes directly to their programs.

See page 18

ARTICLES

46 [CEU] **Physicians, social media, and "BYOD": HIPAA risks and compliance**
by Daniel F. Shay
A security risk assessment and social media policy are essential before you let providers and employees bring their smartphones, tablets, and other devices to work.

53 **Billing compliance for oncology clinical trials in a community cancer center**
by Christina Head and Alaina Underberg
Ensuring timely and accurate billing and record keeping for clinical trials requires coordinating with staff across multiple areas of a medical facility.

56 [CEU] **Ethics in research**
by Juanita Rendon
The increasing scope of international clinical research puts a spotlight on the importance of ethical behavior, not just in the United States, but throughout the world.

61 **Act now, LTC facilities: Phase 2 is upon us**
by Dayna C. LaPlante and Brian D. Bewley
Recommended steps for long-term care facilities to ensure they are ready in eleven areas for the November 28, 2017 deadline for Phase 2 compliance.

66 **Certifying Medicaid program data, Part 1: What it entails and why you do it**
by Jay Davis
To combat fraud, CMS published a final rule that makes Medicare managed care entities responsible for the accuracy, completeness, and truthfulness of data submitted.

70 **Reframing compliance training by a well-formed incentives plan**
by Misty Bridwell
Promote enthusiasm around compliance training with the constructive use of creative communication, rewards and recognition, and elevated status.

72 **Santa Claus: The compliance interview**
by Adam Turteltaub
A light-hearted look at the compliance program at the North Pole.

Compliance TODAY

Compliance Today (CT) (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Subscription rate is $295 a year for nonmembers. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to *Compliance Today*, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

VOLUME 19, ISSUE 12

by Juanita Rendon, CCHW

Ethics in research

» Select the study design that best protects the subjects.
» Obtain independent review approval/oversight before study activities begin.
» Subject selection must be fair and consistent with the scientific purpose.
» Follow the Informed Consent process regulations.
» Use ALCOAC (Attributable, Legible, Contemporaneous, Original, Accurate, and Complete) guidelines in documentation.

Juanita Rendon *(rendonjuanita@yahoo.com) is a Regulatory Compliance Associate at Synexus U.S. Corporate Office in Tempe, AZ.*

With the recent presidential granting of multiple ethics waivers to ex-lobbyists who now work in the White House,[1] and recent changes to regulations governing human subject protections,[2,3] there may not be a better time to review ethical issues relevant to the clinical research field.

Rendon

The increasing scope of international clinical research puts a spotlight on the importance of ethical behavior, not just in the United States, but throughout the world. The Office for Human Research Protection (OHRP) International Program works to ensure that human subjects outside of the United States, who participate in research conducted or funded by U.S. Department of Health and Human Services, receive an equal level of protection as research participants in the United States.

Previous human rights violations have played an important role in the development of the human-rights based approach to health and research. Multiple documents guide the bioethical actions in clinical research studies. Two of these, used in the United States and internationally, are the Belmont Report[4] and the International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice (ICH E6 R2).[5] Both of these documents outline the basic ethical principles in research that involve human subjects. They summarize the foundational ethical principles, guidelines, responsibilities, and expectations for *all* participants involved in the conduct of clinical trials. This article annotates minimal expectations, but not the all-inclusive list, of what is expected from clinical research staff.

Research organizations normally have company ethics/compliance policies and guidelines that employees are required to abide by. These should not be looked at as just corporate policies. They should be viewed as an individual's commitment to holding themselves and coworkers to a higher ethical and legal standard. Strong ethical operating principles are developed to buttress and support the federal and international requirements that guide study conduct for individuals and researchers. Ethical guidelines have been created to protect the rights, welfare, and well-being of human subjects. Ethical protections and procedural requirements, such as appropriate study design, ensuring prior ethics review board approval, equitable selection of subjects, obtaining voluntary informed consent, and quality assurance in documentation are necessary.

Study design

Appropriate study design for a clinical trial will depend on various contextual considerations. What is ethically acceptable in one situation could be problematic in another. In all cases the ethical requirement is to choose a study design that minimizes the risk of harm to research participants while maximizing the benefits. Conflicts of interest may occur when a state entity or patriarchal stakeholder has a part in the conduct of clinical trials. This is particularly important as sponsors from wealthy countries more often use research organizations from low-and middle-income countries to conduct research trials.[6] Selecting a study design that ensures the greatest protection of subjects cannot be separated from the ethical responsibility of research.

Prior review board approval

According to US research regulations and the international research framework, when human subjects are involved in research, an appropriate ethics review committee (Institutional Review Board [IRB]/Research Ethics Committee [REC]) must approve the proposed study protocol, consent forms, and advertising prior to any study conduct taking place. IRBs/RECs have the authority to make these assessments, but are challenged by ethical operating principles that represent vulnerable populations. As developing countries become more globally involved in research, they must confront the normative ethical principles that have long guided studies funded by institutions and industrial sponsors[7] for the last half century. Collaborative studies conducted by federally funded institutions in the U.S. require developing countries' IRBs/RECs to register with the U.S. Office for Human Research Protections and file/acquire a "Federalwide Assurance" application, which is a document that declares compliance with an accepted ethical standard for human research (e.g., Belmont Report, the Helsinki Declaration, or ICH GCP). Sponsors and researchers increasingly choose to conduct research in resource-poor countries for multiple reasons, including fewer financial and regulatory constraints,[8] but this should in no way lower the ethical standards by which research studies are conducted.

Equitable subject selection

Within the confines of the study, subject selection must be equitable, indicating that the benefits and burdens of the research are fairly distributed. Research may not exclude participants on the basis of gender, race, national origin, religion, education, or socioeconomic status, although some of these can play a part in other aspects of ethical protection and protocol procedural requirements. For example, potential participants must be evaluated to determine if they are already part of a population that is burdened by poverty or chronic disability/illness, or may be vulnerable to coercion or undue influence. The selection process must also be evaluated to determine if it overprotects vulnerable participants, such that the opportunity to participate in research is reduced or denied.

Recruitment plans and materials must ensure appropriateness for the population and that they do not use exculpatory language. Research staff are required to recruit in a fair and just manner, weighing the potential benefits to the subjects against their vulnerability and the risks to them. This risk/benefit analysis should be presented to the potential subject as they are, in conjunction with the Principal Investigator(s), the one(s) who decide on study participation.

Informed consent process

The purpose of clinical research trials is to study new medical products in people. It is vital that people who are considering

participating in research understand their role as a "subject"—a living individual from whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual, and (2) identifiable private information.[9] See Chart 1 to answer if an activity would be covered under 45 CFR part 46 and applicable to regulations.[10]

The informed consent requirements are set forth by Federal Drug Administration (FDA) regulations (21 CFR part 50) and apply to research regulated by the FDA. Subjects must understand that they may not necessarily benefit from the clinical trial; they may be exposed to unknown risks; and that entering into a study as a subject is different from being a patient in the standard sense of medical practice. Before enrolling in a clinical research trial, multiple things must be presented to the potential participant, such as:

- adequate information about the study to make an informed decision on whether to participate;
- an appropriate amount of time has been provided to ask questions and discuss the research protocol (plan of research) with the investigative staff and/or family/friends;
- a statement that the study involves research and the purpose of the research;
- a description of all procedures that will take place and any predictable risks or discomforts;
- information about any alternative procedures or treatments that may benefit the research subject;
- contact information of the principal investigator; and
- that they may withdraw consent and stop participating at any time without losing benefits to which they are entitled.

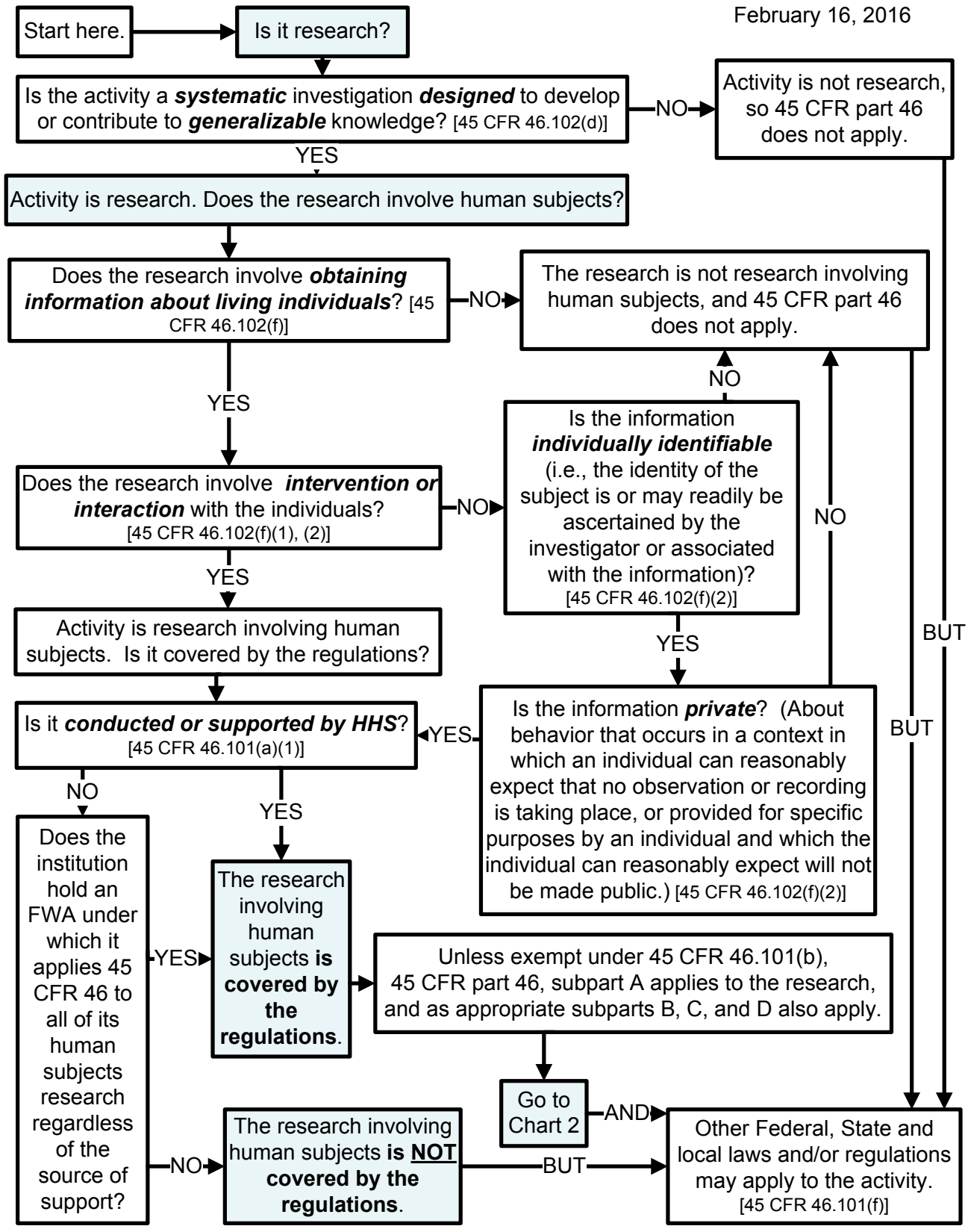
This information should be presented to the potential participants during the process of informed consent, which begins with subject recruitment and includes any advertising used to attract potential subjects into the clinical trial and continues throughout the trial. It is imperative that clinical trials are *voluntary.* Subjects must read the Informed Consent document carefully and be able to ask questions about anything they do not understand or find confusing.[11]

When high-quality data is produced, society can depend on the contribution of science to medical care and health improvements.

Validity in documentation

One of the most common inspection findings by FDA auditors and quality assurance professionals in site inspections is the lack of adequate source documentation. Investigative sites must understand and apply the procedure of good documentation practice (GDP). Producing credible/reliable documentation while protecting the rights and welfare of subjects ensures that study results are built upon a foundation of valid data. GDP is the basis for the integrity of data collection and reporting in the life cycle of clinical research. GDP is required by both the U.S. and the European regulatory authorities, (i.e., the FDAs Code of Federal Regulations and the European Medicines Agency).[12] The way that clinical research is conducted is directly related to the quality of data that is produced. When high-quality data is produced, society can depend on the contribution of science to medical care and health improvements. Valid, high-quality data can only be accomplished if

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?



international, federal, state, and institutional requirements are practiced.

The FDA has long used the acronym-guideline ALCOAC (Attributable, Legible, Contemporaneous, Original, Accurate and Complete). The addition of Complete was incorporated in the guidance effective June 14, 2017 to stand for the fundamental elements of quality and minimum expectations when creating and maintaining trial documentation. Trial documentation is essentially the evidence that regulatory authorities use to make decisions on the release/legalization of new drugs. Any changes in clinical trial records must be traceable, should not obscure the original entry, and should be explained. It is now the explicit responsibility of the Principal Investigator to ensure trial documents follow ALCOAC.[13]

Human society deserves the most moral relationship possible…

Conclusion

The value of scientific contribution to medicine and to quality of life largely depends on how research professionals shape their own future. The linear model of development in research ethics has largely been a result of gross violations in human rights and the protective statement in the Hippocratic corpus "to do good, and not to do harm." The challenge lies between the principal investigator/site staff, the subject, and the disease. Medicine as the social institution that seeks to prevent, diagnose, and treat illness and promote health has an obligate responsibility to uphold and advance ethical provisions in research. Medical ethics are the dynamic moral principles that govern the human conduct about the rightness and wrongness of actions. Holding each other to a human rights-based approach in research will guide the field to a higher ethical and legal standard. Human society deserves the most moral relationship possible, and there are grave risks of serious harm if mitigating actions are not practiced. The minimal expectations annotated in this article can only develop and strengthen the health and research fields.

1. Eric Lipton and Steve Eder: "White House details ethics waivers for ex-lobbyists and corporate lawyers." Politics, *New York Times*, May 31, 2017. Available at http://nyti.ms/2yJHi6V.
2. ICH Interim press release: "ICH releases finalised, draft Guidelines and publishes working party membership for first time" ICH website, October 16, 2017. Available at http://bit.ly/2z4xgjE.
3. HHS: Final revisions to the federal policy for the Protection of Human Subjects (the Common Rule). Available at http://bit.ly/2lbZgM5
4. Department of Health, Education, and Welfare: The Belmont Report. April 18, 1979. Available at http://bit.ly/2y0vGPD
5. ICH: Integrated Addendum to ICH E6(R1) Guideline for Good Clinical Practice (ICH E6 R2). Available at http://bit.ly/2lgrLbJ
6. Joseph J. Amon, Stefan D. Baral, Chris Beyrer, and Nancy Kass: "Human Rights Research and Ethics Review: Protecting Individuals or Protecting the State?" *PLoS Medicine*, Vol. 9, no. 10 (2012). doi:10.1371/journal.pmed.1001325.
7. Robert H. Gilman and Hector H.Garcia: "Ethics review procedures for research in developing countries: a basic presumption of guilt." Commentary, *Canadian Medical Association Journal* 171, no. 3 (2004): 248-49. doi:10.1503/cmaj.1031121.
8. Voo Teck Chuan and G. Owen Schaefer: "Research in Resource-Poor Countries." From *Bioethics Briefings*, The Hastings Center. http://bit.ly/2y34dbc.
9. 45 CFR 46, (revised January 15, 2009). Basic HHS Policy for Protection of Human Research Subjects. http://bit.ly/2gFNDM3
10. HHS: Office for Human Research Protections: Human Subject Regulations Decision Charts, Chart 1. Available at http://bit.ly/2gFqk4K
11. HHS: U.S. Food and Drug Administration: A Guide to Informed Consent-Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators. January 25, 2016. Available at http://bit.ly/2y3xeDw
12. Krishan Kumar: "Good Documentation Practices (GDPs) in Pharmaceutical Industry." *Journal of Analytical & Pharmaceutical Research*, 4, no. 2 (2017). doi:10.15406/japlr.2017.04.00100
13. Ibid, Ref #5