access for U.S. market participants to non-U.S. markets in realization of the global economy and international business. The main substantive amendment in today’s Proposed FBOT Amendments is to Regulation 48.4, which currently permits futures commission merchants (FCMs), commodity pool operators (CPOs), and commodity trading advisors (CTAs) to enter orders on behalf of customers or commodity pools via direct access on a registered FBOT.

As explained in the Proposal, the Commission is proposing to permit introducing brokers (IBs) to submit customer orders via direct access to FBOTs by adding IBs to the list of permissible intermediaries in Regulation 48.4. Doing so would permit IBs to act as executing brokers for U.S. customers that in turn use another intermediary, like an FCM, for clearing and carrying the customer accounts, similar to the way IBs currently perform this service on CFTC-registered designated contract markets (DCMs). Among other benefits, U.S. market participants interested in trading foreign futures could have more choices in brokers and broker arrangements. The Proposed FBOT Amendments will also ensure that customer protections are in place, similar to the current FBOT requirements for FCMS, CPOs, and CTAs.

As sponsor of the CFTC’s Global Markets Advisory Committee (GMAC), I have devoted a significant part of my Commissionership to supporting solutions that will enhance the resiliency and efficiency of global markets. The Proposal is policy that mitigates market fragmentation and the associated impact on liquidity, and promotes the overall competitiveness of our derivatives markets. I am pleased to support the Proposed FBOT Amendments, and I look forward to the public comments.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 50
[Docket No. FDA–2022–D–2997]
Key Information and Facilitating Understanding in Informed Consent;
Draft Guidance for Sponsors, Investigators, and Institutional Review Boards; Availability
AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.
ACTION: Notification of availability.

SUMMARY: The Office for Human Research Protections, Office of the Assistant Secretary for Health (OHRP), and the Food and Drug Administration (FDA) are announcing the availability of a draft guidance entitled “Key Information and Facilitating Understanding in Informed Consent.” This draft guidance provides recommendations related to two provisions of the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule) by the U.S. Department of Health and Human Services (HHS) and identical provisions in FDA’s proposed rule “Protection of Human Subjects and Institutional Review Boards.” FDA’s proposed rule, if finalized, would harmonize certain sections of FDA’s regulations on human subject protections and institutional review boards (IRBs), to the extent practicable and consistent with other statutory provisions, with the revised Common Rule, in accordance with the 21st Century Cures Act (Cures Act). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA’s proposed rule.

DATES: Submit either electronic or written comments on the draft guidance by April 30, 2024 to ensure that FDA and OHRP consider your comment on this draft guidance before the agencies begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions
Submit electronic comments in the following way: Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:

• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2022–D–2997 for “Key Information and Facilitating Understanding in Informed Consent” draft guidance.
This guidance provides recommendations related to two provisions of the revised Common Rule and identical provisions in FDA’s proposed rule “Protection of Human Subjects and Institutional Review Boards” (87 FR 58733, September 28, 2022). The FDA’s proposed rule, if finalized, would harmonize certain sections of FDA’s regulations on human subject protection and IRBs, to the extent practicable and consistent with other statutory provisions, with the revised Common Rule (codified by the Department of Health and Human Services at 45 CFR part 46, subpart A), in accordance with the Cures Act (Pub. L. 114–255, section 3023). The guidance addresses the provisions of the revised Common Rule that require informed consent to begin with key information about the research and to present information in a way that facilitates understanding and identical provisions in FDA’s proposed rule.

In this draft guidance, FDA and OHRP provide recommendations for developing a key information section for clinical trials or studies, including strategies to make consent information as a whole more understandable for prospective research participants. We also provide a sample approach to the key information section that is based, in part, on research regarding patient understanding of information found in labeling for prescription drugs. By using simple phrases and plain language principles, as well as formatting and organizational tools, researchers found that presenting information in a discrete bubble format with topics organized or grouped together can facilitate consumer understanding.1 In the appendix of the draft guidance, we provide an example of a key information section using the bubble format. We encourage interested parties, with input from IRBs, to develop innovative ways to provide key information that will help prospective subjects better understand the reasons why one might or might not want to participate in research.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on “Key Information and Facilitating Understanding in Informed Consent.” It does not establish any rights for any person and is not binding on FDA, OHRP, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.2


2 The Office of the Federal Register has published this document under the category “Rules and Regulations” pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the Federal Register does not affect the content or intent of the document. See 1 CFR 5.1(c).
II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA’s September 28, 2022, proposed rule on “Protection of Human Subjects and Institutional Review Boards” (87 FR 58733), which this draft guidance is intended to interpret, and with previously approved collections of information described in the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule). The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (87 FR 58733 at 58744) and they have been approved under OMB control number 0910–0130. The collections of information in 45 CFR 46 and the final rule entitled, “Federal Policy for the Protection of Human Subjects” (Common Rule) have been approved under OMB control number 0990–0260.

III. Electronic Access


Dated: February 26, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FR Doc. 2024–0826 File 2–29–24 8:45 am]