Agency Guidance Snapshot: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
Guidance for Industry, Investigators, and Other Stakeholders

*The Yale Human Research Protection Program (HRPP) has launched the "**Agency Guidance Snapshot**" series. The purpose of the Agency Guidance Snapshots is to highlight recent agency guidance from the Food and Drug Administration (FDA)[1], Office for Human Research Protections (OHRP), and other federal agencies that specifically impacts Yale University and affiliate stakeholders who conduct or oversee **human subjects research.***

Please Note: Yale University does not expect any immediate changes to policies due to this guidance; however, this guidance will be taken into consideration as policies and procedures are reviewed and revised in the future. Yale University may have additional requirements related to the topics covered in this guidance. For more information, please refer to the following Yale University Human Research Protection Program (HRPP) documents located on the HRPP website (Policies, Procedures, Guidance, and Related Documents) and in the Yale HRPP IRES-IRB Library (IRES IRB LOGIN): **1)** Yale HRPP Policy and Standard Operating Procedure Manual; **2)** Yale HRPP Investigator Manual; **3)** Yale IRB Members and Chairs Manual**;** and **4)** HRPP Supplemental Guidance Manual. Please also refer to University Policies & Procedures and policies published by the various Yale University schools and departments.

Title of Document:	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations
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Stakeholders Impacted:	Investigators ☒ Sponsors ☒ Sponsors-Investigators ☒ IRB/HRPP Staff, Chairs, & Members ☒ Other ☐
Hyperlink to Document:	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

Overview of Guidance Document:

A **digital health technology** (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for health care and related uses. This guidance provides recommendations for sponsors, investigators, and other stakeholders on the use of DHTs for remote data acquisition from participants in clinical investigations that evaluate medical products.

[1] FDA Guidance documents represent the Agency's current thinking on a particular subject. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

There is a large spectrum of DHTs available for potential use in a clinical investigation. DHTs for remote data acquisition in clinical investigations can include hardware and/or software to perform one or more functions.

DHTs can be used for remote data acquisition in clinical investigations, such as wearables and software applications (including mobile apps). Depending on the intended use of a DHT, the DHT may meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2] Devices intended for use in clinical investigations, including DHTs, are exempt from most regulatory requirements applicable to devices, including marketing authorization, as long as the investigation complies with applicable requirements under 21 CFR part 812.

This guidance provides recommendations for ensuring that a DHT is fit-for-purpose (i.e., that the level of validation associated with the DHT is sufficient to support the use, including the interpretability of its data in the clinical investigation), which involves considerations of both the DHT's form (i.e., design) and function(s) (i.e., distinct purpose(s) within an investigation). DHTs may rely on or work with other technologies that support their operation, such as general-purpose computing platforms (e.g., smartphones) and communication networks. Therefore, when implementing the recommendations in this guidance related to DHTs, sponsors should ensure that these other technologies are adequate to support the function(s) of the DHT. The recommendations in this guidance may be relevant to the other technologies used to support remote data acquisition in a clinical investigation.

This guidance outlines recommendations intended to facilitate the use of DHTs in clinical investigations as appropriate for the evaluation of medical products. These recommendations include the following topics:

- Selection of DHTs that are suitable for use in clinical investigations;
- Identification and management of risks associated with the use of DHTs during clinical investigations; and
- Roles of sponsors and investigators related to the use of DHTs in clinical investigations.

Key Points for All Stakeholders – Investigators, Sponsors, Sponsor-Investigators, and IRB/HRPP Staff, Chairs, & Members:

The ability to capture and transmit data remotely increases opportunities for individuals to participate in clinical investigations where some or all of the trial-related activities occur at locations other than traditional clinical trial sites (decentralized clinical trials). Increasing access to and use of DHTs in clinical trials can potentially enable the inclusion of diverse and underrepresented populations by facilitating decentralized clinical trials. This could help to ensure medical products are safe and effective for the population for which they will be used. Reducing the burden on trial participants can also improve trial recruitment, participant engagement, and retention throughout the study. Moreover, use of DHTs in clinical investigations may facilitate inclusion of certain participants with physical or cognitive disabilities or pediatric participants. For example, the use of sensors may be of value to obtain data about signs (e.g., scratching, sleep) from cognitively impaired or pediatric participants who are unable to report symptoms (e.g., itch, insomnia). Sponsors should consider what impact the use of a DHT in a clinical investigation could have on the cohort participating (e.g., expanding participation of geographically dispersed individuals, limiting participation of those unwilling to use DHTs).

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[2] See section 201(h) of the FD&C Act for the **definition of a *device***. How to determine whether a DHT proposed for use in a clinical investigation meets the definition of a device under the FD&C Act is outside the scope of this guidance. For further information about FDA digital health regulatory policies, see https://www.fda.gov/medical-devices/digital-health-center-excellence/ask-question-about-digital-health-regulatory-policies.

A. Considerations when Using Digital Health Technologies in Clinical Investigations

The following are some specific issues that should be considered when selecting a DHT for a clinical investigation:

1. Clinical Trial Population
    - Among other characteristics, education, language, age, health/physical condition, and technical aptitude of trial populations should be considered to ensure that trial participants will be able to use the DHT as intended for the purposes of the trial and to facilitate inclusion of diverse populations in whom the product is intended to be used.

2. Technical and Performance Specifications
    - To select the appropriate DHT for a clinical investigation, the sponsor should identify the minimum technical and performance specifications of the DHT. If applicable, the sponsor should identify a specific product or products (e.g., model and/or version) that meet the minimum technical and performance specifications for a DHT to remain fit-for-purpose.

3. Design and Operation of DHTs and Other Technologies
    - DHT design (size, portability) and ease of use may influence whether trial participants will use it for the duration of clinical investigation, which is particularly important for DHTs that are wearable. Power needs and operational specifications, as well as network system availabilities (for both participants and sponsors) should be anticipated. Safeguards should be in place to manage cybersecurity risks, prevent unauthorized access to the DHT and the data it collects, and ensure privacy and security.

4. Use of a Participant's Own DHT and/or Other Technologies
    - Sponsors should evaluate the advantages and disadvantages of allowing trial participants to use their own DHTs (e.g., continuous glucose monitors) and/or other technologies (e.g., general-purpose computing platforms such as smartphones and tablets) for remote data acquisition in a clinical investigation.

B. Risk Considerations When Using Digital Health Technologies

Sponsors, investigators, and institutional review boards (IRBs) should consider any risks to trial participants associated with use of the DHTs for data collection. The risks of using a DHT in a clinical investigation can generally be broadly categorized as clinical risks and privacy-related risks, although there is some overlap between these two areas. The following sections describe some of the risks pertaining to the use of DHTs that, depending on the specific design of the clinical investigation and DHTs used, may need to be assessed by the IRB, communicated in the informed consent document, and addressed by the sponsor in the submission.

1. Clinical Risks
    - The physical features of the DHT should be evaluated for discomfort and risk of injury (e.g., wrist band occluding blood supply, skin contacting components causing skin irritation). Evidence from safety testing and usability evaluations conducted by the DHT manufacturer, if available, or the sponsor of the clinical investigation may be helpful to show that risks associated with use of a DHT by trial participants are minimized.

- When measurements made by DHTs (e.g., glucometers) are used as the basis to modify the administration of the investigational product or the treatment of trial participants, it is critical to evaluate the risk of erroneous measurements resulting in excessive, inadequate, or inappropriate treatment.
- Sponsors should consider cybersecurity threats that could potentially impact the functionality of the DHT, resulting in a clinical risk to participants (e.g., corrupting the output of a continuous glucose monitor).

2. Privacy-Related Risks

Sponsors, investigators, and IRBs should be aware that unique privacy risks may arise when DHTs are used in a clinical investigation. The following should be considered, as applicable:

- The risk of potential disclosure of personally identifiable information or participant locations via a breach of the DHT or associated data storage, such as a durable electronic data repository.
- DHTs or other technologies may have end-user licensing agreements or terms of service that allow sharing of data with other parties, such as the manufacturer of a general-purpose computing platform used by a DHT. Potential trial participants should be informed about who will have access to their trial data if they decide to participate.
- Sponsors should ensure that appropriate security safeguards are in place to secure data at rest and in transit to prevent access by intervening or malicious parties (e.g., cybersecurity threats).

3. Informed Consent Regarding Risks

FDA regulations at 21 CFR part 50 set forth the requirements for obtaining the informed consent of participants in clinical investigations. DHTs can be used to obtain electronic informed consent in a clinical investigation.[3] Considerations for what information to convey in the informed consent process regarding the DHT being used in a clinical trial include, as applicable:

- Reasonably foreseeable risks or discomforts related to the use of the DHT in the clinical investigation. Information regarding what may be done to mitigate serious risks, and risks and discomforts more likely to occur, should also be considered for inclusion.
- Use of the DHT during the clinical investigation may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) which are currently unforeseeable.
- The type of information that will be collected by the DHT and how that information will be used and monitored. When relevant, participants should be informed of what action to take in case of any concerning sign, symptom, or abnormal clinical event (e.g., hypoglycemia or abnormal cardiac rhythm) detected by a DHT, such as seeking emergency medical attention.
- Who may have access to data collected through the DHT during or after the clinical investigation (e.g., sponsors, investigators, participants, DHT manufacturers, other specified third parties) and during what time frame.
- Who outside of the clinical investigation may have access to participants' data.
- Measures to protect participant privacy and data, and limitations to those measures, when DHTs are used.
- Added costs, which could include costs for the participants that may result from using the DHT during the clinical investigation (e.g., data use charges).

[3] See the guidance for IRBs, investigators, and sponsors *Use of Electronic Informed Consent Questions and Answers* (December 2016). See also the guidance for IRBs, clinical investigators, and sponsors *Informed Consent* (August 2023), section V, question 10 regarding electronic informed consent.

C. Roles of Sponsors and Investigators Related to the use of DHTs in Clinical Investigations

To help ensure the quality and integrity of data, adequate protection of participants, and satisfaction of regulatory requirements applicable to clinical investigations, sponsors and investigators should consider the following recommendations with respect to clinical investigations that involve use of a DHT to remotely acquire data:

- Develop and ensure training for trial personnel and trial participants on using DHTs according to the protocol.
- Develop a plan for technical assistance to trial participants or trial personnel for all DHTs used during the trial.
- Develop a risk management plan to address potential problems trial participants may experience when using a DHT or other technology during a clinical investigation.
- Develop a safety monitoring plan as part of the protocol that includes how frequently investigators will review continuous data, if applicable; under what circumstances and how participants will be informed of abnormal findings detected by the DHT; and what action participants should take in case of any concerning sign, symptom or abnormal clinical event.

For more related information, please see the following links to additional resources:

- FDA Guidance Documents
- FDA Focus Area: Digital Health Technologies
- Secretary's Advisory Committee on Human Research Protections web page "Attachment B - Clarifying Requirements in Digital Health Technologies Research," available at https://www.hhs.gov/ohrp/sachrp-committee/recommendations/april-7-2020-attachment-b/index.html.
- CITI Program: FDA Releases Guidance on Digital Health Technologies

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