

# Clinical Research in the Health Center Setting: Managing Legal and Compliance Risks

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# Clinical Research in the Health Center Setting: Managing Legal and Compliance Risks

## Health centers and their patients are in a unique position to contribute to clinical research:

- Health centers have built trusting relationships with their patients and the communities they serve. As early developers and adopters of electronic medical records systems, health centers maintain an abundance of health information about their patients.
- Health centers recognize that partnering with academic medical centers and hospitals on research can improve patient outcomes and experience, reduce health disparities, improve care delivery, and increase access to specialty care for patients, as well as provide additional resources for the health center and develop academic partnerships to support activities outside research.<sup>1</sup>
- Many health centers have built their internal research capacities, creating research departments and receiving federal funding to support their research priorities.
- Health center patients include members of groups historically underrepresented in research—members of racial/ethnic minority groups, individuals in low income and medically underserved communities as well as vulnerable populations, including individuals who are chronically ill, do not speak English, are refugees, or who do not have a home.
- Recent government and private research initiatives have focused on increasing diversity in research, including, for example, the National Institutes of Health *All of Us* Research Program.<sup>2</sup>
- The Patient-Centered Outcomes Research Institute (PCORI), an independent, federally-funded, nonprofit, engages with community health centers when it to sponsor research.<sup>3</sup>

This Issue Bulletin describes legal and compliance risks that health centers should consider before engaging in research opportunities, including an overview of the federal regulations that protect research participants; the application of federal fraud, waste and abuse laws in research; and the malpractice, insurance and Federal Tort Claims Act (FTCA) considerations.<sup>4</sup> While there are risks to participating in research for health centers and their patients, there are also rewards that reach beyond the health centers and patients directly involved and provide benefits to the public. This Issue Bulletin provides health centers with a framework to evaluate research opportunities and suggests steps to mitigate the legal and compliance risk.

- 1 See Brandt, H. M., Young, V. M., Campbell, D. A., Choi, S. K., Seel, J. S., & Friedman, D. B., *Federally Qualified Health Centers' Capacity and Readiness for Research Collaborations: Implications for Clinical-Academic-Community Partnerships*, *Clinical and translational science*, 8(4), 391–393 (2015), available at <https://doi.org/10.1111/cts.12272>.
- 2 For more information, see <https://allofus.nih.gov/>.
- 3 See Patient-Centered Outcomes Research Institute (PCORI), “Engaging Patients as Partners in Patient Centered Outcomes Research in the Primary Care Safety Net” available at <https://www.pcori.org/research-results/2018/engaging-patients-partners-patient-centered-outcomes-research-primary-care>. By statute, Congress established PCORI as an independent nonprofit organization incorporated in the District of Columbia for specific purposes. For example, PCORI funded the development of PCORnet®, the National Patient-Centered Clinical Research Network, by convening FQHC in a project led by a Principal Investigator and one health center. While PCORI is federally funded, it is not itself a federal agency.
- 4 This Issue Bulletin does not address a health center’s potential liability to participants who are harmed as a result of participation in a study. Lawsuits against investigators, institutional review boards, and research institutions can occur. Under U.S. federal regulations, participants providing informed consent must receive information regarding whom to contact in case of a research-related injury. This bulletin highlights the importance of the informed consent processes generally. This Issue Bulletin is centrally concerned with limiting risk before commencing research, rather than research-related complaints made by participants.

## PROTECTIONS FOR HUMAN SUBJECTS IN RESEARCH

Federal statute<sup>5</sup> requires any entity applying for a grant, contract or cooperative agreement from the U.S. Department of Health and Human Services (HHS) in support of biomedical or behavioral research involving human subjects to have such research reviewed in order to protect the rights of the human subjects.

The “Basic HHS Policy for the Protection of Human Research Subjects” regulations contain provisions for protecting human subjects, such as compliance assurances, review board requirements and procedures, and informed consent.<sup>6</sup> These regulations are referred to as the “Common Rule” because they have been codified by multiple federal departments and agencies.<sup>7</sup>

The Food and Drug Administration (FDA) is not, however, a Common Rule agency—it has separate regulations<sup>8</sup> that apply to the products under its jurisdiction (drugs, biological products and medical devices) and the FDA regulations apply regardless of whether the research is federally or privately funded.

In 2016, the 21<sup>st</sup> Century Cures Act required the Secretary of HHS to harmonize the differences between the HHS human subject regulations and the FDA’s human subject regulations to increase the efficiencies of the clinical trial system, reduce ambiguity in interpretation of the regulations, protect vulnerable populations, and alleviate the burden on clinical investigators.<sup>9</sup> In 2018, the HHS Office of Human Research Protections (OHRP) revised the Common Rule accordingly.

5 42 U.S.C. § 289. Notably, with respect to several issues, the federal research regulations rely on state laws to provide relevant definitions or other elements essential to interpretation and application of the regulations. For example, the regulations define “children” at 45 CFR 46.402(a) as those persons who have “not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” An analysis of the state law issues with respect to research and informed consent falls outside of this particular bulletin.

6 45 C.F.R. Part 46; see also HHS Summary of the Federal Policy for the Protection of Human Subjects (“Common Rule”), available at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>.

7 Human subjects research conducted or supported by each U.S. federal department or agency that has adopted the Common Rule is governed by the regulations as implemented by the respective department or agency. According to the HHS Office of Human Research Protections, 20 departments and agencies (including HHS, the Social Security Administration, the Department of Housing and Urban Development, and the Department of Veterans Affairs) intend to follow the 2018 Common Rule. For a list of all the departments and agencies with links to their regulations, see <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>.

8 21 C.F.R. Parts 50, 56, 312, and 812. If a research project is conducted or supported by HHS and involves an FDA-regulated product, then the study is subject to both sets of regulations and, where the regulations differ, the regulations providing the greater protection to the human subjects should be followed. See “Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations Guidance for Sponsors, Investigators, and Institutional Review Boards”, U.S. Department of Health and Human Services, Food and Drug Administration, Office of Good Clinical Practice (OGCP) October 2018, available at: <https://www.fda.gov/media/117042/download>.

9 Section 3023 of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255).

## DETERMINING WHETHER THE COMMON RULE APPLIES

FEDERAL AGENCIES SUBJECT TO THE COMMON RULE
Agency for International Development
Central Intelligence Agency
Consumer Product Safety Commission
Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Health and Human Services <ul style="list-style-type: none"><li>• NIH</li><li>• SAMHSA</li><li>• HRSA etc.</li></ul>
Department of Housing and Urban Development
Department of Justice
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
National Aeronautics and Space Administration
National Science Foundation

When presented with a research opportunity or upon identifying a research opportunity, health centers should determine what federal regulations, if any, apply. As a general matter, the federal agencies above have adopted the Common Rule and it applies to research they fund. In addition, some other independent nonprofits chose to adopt policies that expressly refer to the Common Rule standards for protections of human subjects. In the request for grant proposals and the notice of award, a sponsor or funder may expressly state that the Common Rule applies to the funded activities.

Health centers involved in PCORI funded research should note that the nonprofit's policy states that it expects grantees to "comply with the US Department of Health and Human Services' (HHS) Federal Policy for the Protection of Human Subjects, reflected in HHS regulation 45 C.F.R. Part 46."<sup>10</sup>

10 See PCORI Protection of Human Subjects Policy available at <https://www.pcori.org/blog/addressing-protection-human-subjects-pcori-applications-and-merit-review>.

## DETERMINING WHETHER ACTIVITY INVOLVES RESEARCH

To determine whether the Common Rule applies to a health center's research activities, the OHRP suggests<sup>11</sup> organizations answer the following questions:

1. Does the activity involve **research**? The Common Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>12</sup> The 2018 Rule excluded certain activities, including “public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.”<sup>13</sup> We provide a chart to aid in this determination.
2. While HRSA programs are not generally described as research programs, some HRSA service delivery and demonstration programs may be designed to contribute to “generalizable knowledge” and would be considered “research” as defined by the Common Rule.

One common question arises about the difference between quality improvement (QI) versus research. While “most quality improvement efforts are not research,” health centers that believe proposed QI may also be research should review OHRP's frequently asked questions on the topic.<sup>14</sup> Four categories of activities that are outside the Common Rule definition of research.

### EXPLICITLY DEEMED OUTSIDE THE DEFINITION OF RESEARCH AT 45 CFR 46.102(L)(1-4).

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3. Does the research involve **human subjects**? The Common Rule defines a human subject as “a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”<sup>15</sup> For example: Health centers may be involved in human subjects research and activities subject to the Common Rule if they obtain information or biospecimens from patients. Such information could be part of different types of basic, clinical or translational research being performed with a partner research institution.

11 See OHRP's “Human Subject Regulations Decision Charts: 2018 Requirements” available at <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>. The charts do not address requirements that may be imposed by other organizations, such as the FDA, other sponsors, or state or local governments.

12 45 C.F.R. § 46.102(l).

13 45 C.F.R. § 46.102(l)(1)-(4).

14 OHRP's “Quality Improvement Activities FAQs” available at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>.

15 45 CFR § 46.102(e)(1).

## WHAT IS THE DIFFERENCE BETWEEN BASIC, CLINICAL AND TRANSLATIONAL RESEARCH?<sup>16</sup>

Translational research: When scientific research is integrated into clinical applications.

Clinical research: Research intended to examine whether new treatments, medications and diagnostic techniques are safe and effective in patients.

Basic research: When science is carried out to increase understanding of fundamental principles and mechanisms which often do not have immediate practical applicability.

4. Is the research involving human subjects **conducted or supported by HHS**? Human subjects research supported by a grant or contract from HHS is supported by HHS. Human subjects research supported entirely by a private company, foundation, or individual donor is not considered conducted or supported by HHS; however, other federal regulations (like the FDA regulations mentioned earlier) or state regulations, could apply.
5. Is the human subjects research conducted or supported by HHS **exempt**? The Common Rule exempts eight types of research activities from complying with the Common Rule,<sup>17</sup> including an exemption for research and demonstration projects conducted or supported by a federal department or agency “designed to study, evaluate, improve or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.”<sup>18</sup>

Although studies that qualify for exempt status do not have the same federal requirements under the Common Rule, investigators still have a responsibility to protect the rights and welfare of their subjects and conduct their research in accordance with other federal laws and an institution’s policies. Researchers may inquire as to who is authorized to determine that activities involve research or are exempt under the Common Rule. The regulations do not specify; however, health centers may want to implement human subjects research exemption policies to establish roles and responsibilities for such determinations.

## CATEGORIES OF EXEMPT RESEARCH—42 C.F.R. § 46.104(D)

Category 1: Research in Established or Commonly Accepted Educational Settings

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects

Category 4: Secondary Research for Which Consent is Not Required

Category 5: Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required

Category 8: Secondary Research for Which Broad Consent is Required

6. Is the institution **engaged** in human subjects research? An institution is generally considered engaged in human subjects research when:

16 See Dana Farber Cancer Institute, “Basic, Clinical and Translational Research: What’s the Difference?” available at <https://blog.dana-farber.org/insight/2017/12/basic-clinical-translational-research-whats-difference/>.

17 45 CFR § 46.104(d).

18 45 CFR §46.104(d)(5).

- It receives a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research, even if all activities involving human subjects are carried out by employees or agents of another institution
- Its employees or agents:
  - Obtain data about the subjects of the research through intervention or interaction
  - Obtain identifiable private information from any source about the subjects of the research
  - Interact for research purposes with any human subject of the research
  - Obtain the informed consent of human subjects for the research.<sup>19</sup>

## ASSURANCES OF COMPLIANCE & INSTITUTIONAL REVIEW BOARDS: COMPLIANCE WITH THE COMMON RULE

Health centers engaged in non-exempt human subjects research conducted or supported by HHS must satisfy the Common Rule requirements related to assurances of compliance and institutional review board (IRB) review and approval. If a health center partners with another institution or entity on research to which the Common Rule applies, some of the Common Rule requirements will apply to the health center.

**Assurance of Compliance:** Before engaging in non-exempt human subjects research conducted or supported by HHS, an institution must hold, obtain or be otherwise covered by an OHRP-approved Federalwide Assurance (FWA).<sup>20</sup>

Under the FWA, the institution must have a statement of principles on protecting human subjects to guide its research activities, designate an IRB to review research, designate a Human Subjects Administrator and comply with the FWA Terms of Assurance.<sup>21</sup> Once OHRP approves the terms of the FWA, the terms constitute binding commitments. Other federal departments and agencies that have adopted the Common Rule may rely on the FWA for research they conduct or support.

- The FWA must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA.
- If the health center directly receives an HHS award to support human subjects research, it must submit an FWA.<sup>22</sup>
- If another entity is the direct recipient of the HHS award, that other entity must hold an OHRP-approved FWA and it *may* extend the applicability of the FWA to the health center as a collaborating investigator.<sup>23</sup>
- An extension of an FWA to cover the health center should be documented using an Individual Investigator Agreement (IIA).<sup>24</sup>

19 See OHRP's "Engagement of Institutions in Research" (2008) available at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>.

20 45 C.F.R. § 46.103(a).

21 A copy of the FWA Form to 2020 (approved for use through August 31, 2023) is available at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/fwa-form-2017/index.html>. A copy of the FWA Terms of Assurance is available at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.html>.

22 Details on filing a new FWA or updating/renewing an FWA are available at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html>.

23 For more information on extending FWA coverage to collaborating investigators, including a link to a sample individual Investigator Agreement, see "Extending an FWA to Cover Collaborating Investigators" OHRP (2005): <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html>

24 A sample IIA is available at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/individual-investigator-agreement/index.html>.

If a health center routinely engages in non-exempt human subjects research with other entities that are direct recipients of an HHS award, OHRP guidance suggests the health center obtain its own OHRP-approved FWA, instead of relying on an IIA. If an institution is uncertain about the need for its own FWA, it may consult with OHRP.

IRB TYPES AND RELATED DEFINITIONS	
Local Institutional Review Boards	Local IRBs are affiliated with the institution or organization conducting the research (for example, a university or hospital) and are usually located in or near the study site.
Central Institutional Review Boards	Central IRBs are used with research that involves large, multisite clinical trials (for example, cancer research conducted at different places) that go beyond the expertise that may exist in the local community.
Commercial or Independent Institutional Review Boards	Commercial or independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects. The use of commercial review boards recently has become more common.
External Reviewing Institutional Review Boards	The “IRB of record” that a health center may rely upon for review under the Common Rule. Review and oversight may be ceded by the health center on a project-by-project basis under a Reliance Agreement.
Reliance Agreement	A formal, written agreement that provides a mechanism by which one institution or individual engaged in research delegates IRB oversight to an independent IRB, or an IRB of another institution. Institutions may use different terms for this kind of agreement, e.g. reliance agreement, IRB authorization agreement (IAA), individual investigator agreement (IIA), or memorandum of understanding (MOU).
Community Research Review Boards	Established to determine whether and how research is conducted in communities, community-based boards review processes and operate independently, in parallel or in partnership with IRBs. These boards routinely examine issues that IRBs typically do not (e.g. community risks and benefits of research and cultural competency). In limited circumstances, these entities operate as community based-IRBs (though, they may not necessarily handle all research reviews as required under the Common Rule for the health center). <sup>25</sup>

**Institutional Review Board (IRBs):** To protect human subjects in research, the Common Rule requires the research to be reviewed, approved, and monitored by an IRB.<sup>26</sup>

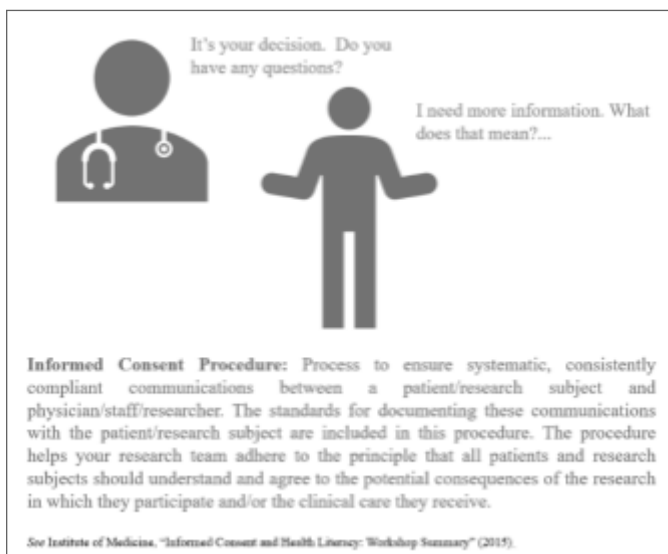
25 Albert Einstein College of Medicine, The Bronx Health Link and Community-Campus Partnerships for Health “Community IRBs & Research Review Boards: Shaping the Future of Community-Engaged Research” available at [https://www.ccphealth.org/wp-content/uploads/2017/10/Shaping\\_the\\_Future\\_of\\_CEnR.pdf](https://www.ccphealth.org/wp-content/uploads/2017/10/Shaping_the_Future_of_CEnR.pdf) (2012).

26 The comparable FDA regulations (21 C.F.R. parts 50 and 56) require that FDA regulated research involving human subjects is reviewed and approved by such an IRB.



- *IRBs and Health Centers:* A health center may rely on another institution's IRB to review its research, if the parties execute an IRB authorization agreement (also known as a reliance agreement).<sup>27</sup> For example, a health center may execute an IRB authorization agreement with an academic medical center or hospital that maintains an internal IRBs to review the research of the investigators affiliated with their institutions.
- There are also independent or commercial IRBs, as well as IRBs in managed care organizations, in government agencies, and in independent nonprofit entities. The IRB authorization agreement must be kept on file at both organizations and made available upon request to OHRP or any federal department or agency conducting or supporting the research.
- Alternatively, a health center may establish and maintain its own IRB. The IRB must be registered with OHRP and must meet the regulatory requirements relating to membership, functions, policies, documentation, etc.<sup>28</sup>
- In recent years, many health centers have developed community research boards to provide input on research priorities. A health center's community research board is unlikely, however, to meet the IRB requirements unless it was intentionally designed to also serve as an IRB.

**Levels of IRB Review and Approval:** There are three levels of IRB Review—full board review, expedited review, and exempt from continuing IRB review.<sup>29</sup> The level of review is determined by the level of potential risk to human subjects and the vulnerability of the subject population (*e.g.*, children and prisoners). When reviewing human subjects research, an IRB has the authority to approve it, to require modification in order to secure approval or to disapprove it.<sup>30</sup>



- 27 A sample IRB Authorization Agreement is available at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwaf/forms/irb-authorization-agreement/index.html>. A master IRB reliance agreement from the SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform) website is available at: <https://smartirb.org/agreement/>.
- 28 For example, the Common Rule requires IRB members to have sufficient experience and expertise, and to reflect the diversity of the community, in order "to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." Members are prohibited from participating in the IRB's initial or continuing review of any project in which the member has a conflict of interest. See 45 C.F.R. § 46.107.
- 29 The categories of exempt research are listed at 45 C.F.R. § 46.104(d) and include certain educational research, benign behavioral interventions and research and demonstration projects conducted and supported by a Federal department or agency. Research subject to expedited review involve no more than minimal risk that meet the federal expedited review criteria (*e.g.*, use of data already collected for non-research purposes) which are reviewed by the IRB chair or experienced IRB reviewer(s) designated by the chair, as described at 45 C.F.R. § 46.110.
- 30 45 C.F.R. § 46.109(a).

To be approved, an IRB must find the research protocol meets certain requirements, including the following:

- The risks to subjects must be minimized, be reasonable in relation to the anticipated benefits to the subjects and the knowledge expected from the research and the selection of subjects must be equitable.<sup>31</sup>
- **An informed consent process must be established.**<sup>32</sup> According to OHRP, informed consent is more than having a prospective subject sign a form—it is a process that begins with the initial communication about the research project and continues until the end of the research study. The informed consent process, whether oral or written, provides prospective subjects with “information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.”<sup>33</sup>

The informed consent procedure can help to build trust with potential research participants.

Informed consent must begin with a concise and focused presentation of key information, organized and presented in a way that facilitates comprehension, to assist the subject in understanding the reasons for participating in the research and the reasons for not participating in the research.<sup>34</sup>

The informed consent must include certain basic elements<sup>35</sup> and it must *not* contain a waiver or appearance of a waiver of the subject’s legal rights, or releases or appearances to release the investigator, sponsor, institution or its agents from liability for negligence.<sup>36</sup>

#### CHECKLIST—THE BASIC ELEMENTS OF INFORMED CONSENT AT 45 CFR §46.116(B) INCLUDE:

- A statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject’s participation; a detailed description of the procedures to be followed; and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and the research subject’s rights, and whom to contact in the event of research-related injury;

31 45 C.F.R. § 46.111(a)(1)-(3).

32 45 C.F.R. § 46.111(a)(4)-(5). See e.g. Boston Children’s Hospital, “Informed Consent/Assent” documents available at <https://www.childrenshospital.org/research/institutional-review-board/guidelines-and-policies>.

33 45 C.F.R. § 46.116(a)(4).

34 45 C.F.R. § 46.116(a)(5).

35 45 C.F.R. § 46.116(b).

36 45 C.F.R. § 46.116(a)(6).

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- If the research involves the collection of identifiable private information or identifiable biospecimens, a statement as to how the information or biospecimens will or will not be used or distributed, with or without identifiers, for future research studies.

In addition, 45 CFR §46.116(c) contains additional elements for informed consent that must be conveyed to the subject if determined appropriate by the IRB. These elements include:

- A statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus), which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of the subject's decision to withdraw from the research and procedures for the orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may affect the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

An IRB may modify/alter the consent requirements under 45 CFR §46.116(f) if the IRB finds and documents that:

- The research involves no more than minimal risk to the subject;
- The research could practicably be performed without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- The subjects will be provided with additional pertinent information whenever appropriate.

## IRB WAIVER OF INFORMED CONSENT

An IRB may waive or alter the informed consent requirements in certain circumstances, which must be documented,<sup>37</sup> including:

- If the research or demonstration project is conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine public benefit or service programs and procedures, as well as alternatives to such programs and procedures, and the research could not be carried out without the waiver of alteration.<sup>38</sup>
- If the research involves no more than minimal risk to the subjects, it could not be carried out within the waiver or alteration, use of identifiable private information or biospecimens is required; the waiver or alteration will not adversely affect the rights and welfare of the subjects; and the subjects are provided with additional pertinent information after participation, whenever appropriate.<sup>39</sup>
- There must be provisions for monitoring data to ensure the safety of subjects.<sup>40</sup>

### *IRB Privacy Considerations*

- **There must be provisions to protect the privacy of subjects.** The IRB must ensure that there are adequate provisions to protect the privacy of subjects.<sup>41</sup> An IRB (or Privacy Board) may waive or alter the authorization requirements for the use or disclosure of protected health information (PHI) under the HIPAA Privacy Rule if it determines the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals; the research could not practicably be conducted without the waiver or alteration; and the research could not practicably be conducted without access to and use of the PHI.<sup>42</sup>

When the HIPAA authorization requirements have been waived or altered, the health center must obtain the following documentation prior to using or disclosing the PHI:

- Identification of the IRB and the date on which the alteration or waiver of authorization was approved;
- A statement that the IRB determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria required for waiver;
- A brief description of the PHI for which use or access has been determined to be necessary by the IRB;
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the chair or other member, as designated by the chair, of the IRB.<sup>43</sup>

The HIPAA Privacy Rule also permits covered entities to use or disclose PHI without authorization if the use or disclosure of PHI is necessary to prepare a research protocol or the use of disclosure is for research on the PHI of decedents.<sup>44</sup>

37 For additional guidance on informed consent, see Office for Protection from Research Risks' "Informed Consent Tips" (1993), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html#:~:text=Informed%20consent%20is%20a%20process,consent%20for%20a%20voluntary%20act>.

38 45 C.F.R. § 46.116(e)(3).

39 45 C.F.R. § 46.116(f)(3).

40 45 C.F.R. § 46.111(a)(6).

41 45 C.F.R. § 46.111(a)(7).

42 45 C.F.R. § 164.512(i)(2)(ii).

43 45 C.F.R. § 164.512(i)(2).

44 45 C.F.R. § 164.512(i)(1)(ii) and (iii).

If the use or disclosure of PHI for research purposes does not fit into an exception, the subject must complete a HIPAA-compliant authorization.<sup>45</sup> The federal regulations protecting the confidentiality of substance use disorder patient records (42 CFR Part 2) permit the disclosure of patient identifying information without patient consent for the purposes of scientific research if certain conditions are met.<sup>46</sup>

## IRB Confidentiality Concerns

**Maintaining confidentiality of data:** The informed consent must include a “statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.”<sup>47</sup>

- **Additional safeguards for subjects likely to be vulnerable to coercion or undue influence.** When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB will determine whether additional safeguards have been included in order to protect the rights and welfare of these subjects.<sup>48</sup>

During the COVID-19 pandemic, OHRP provided guidance regarding activities exempt from IRB review, including whether COVID-19-specific diagnostic tests, other medical devices or therapeutics require IRB review.

## Links to Recent Guidance for Research During the Pandemic.

HRSA	• FTCA requirements related to clinical trials, <a href="#">visit COVID-19 Frequently Asked Questions</a> . <sup>49</sup>
OHRP	• In response to questions from the research community, OHRP offers guidance regarding the regulatory requirements at 45 CFR part 46 <a href="#">here</a> . <sup>50</sup>
FDA	• The FDA issued COVID 19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders <a href="#">here</a> . <sup>51</sup>

## IRB MONITORING

Following initial approval, IRBs must periodically review research at intervals appropriate to the degree of risk and, unless the IRB determines otherwise, the periodic review must happen not less than once per year.<sup>52</sup> The continuing review must be substantive and meaningful, satisfying the same criteria to initially approve the research.

Proposed changes to the research must be promptly reported to the IRB for review and approval except when a change is necessary to eliminate an immediate hazard to the subjects of the study.<sup>53</sup> An expedited review procedure may be used if there is only a minor change in previously approved research.<sup>54</sup>

45 The authorization requirements include several special provision that apply to authorizations for research, including permitting compound authorizations (45 C.F.R. § 164.508(b)(3)(i)), conditioning the provision of research-related treatment on an authorization (45 C.F.R. § 164.508(b)(4)), and allowing the expiration date or event to state “end of the research study,” “none” or similar language (45 C.F.R. § 164.508(c)(1)(v)). The HIPAA Privacy Rule also includes special provisions that apply to research and relate to a patient’s right of access (45 C.F.R. § 164.524(a)(2)(iii)) and accounting of disclosures (45 C.F.R. § 164.528(b)(4)).

46 42 C.F.R. § 2.52(a).

47 45 C.F.R. § 46.116(b)(5).

48 45 C.F.R. § 46.111(b).

49 [https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions?field\\_faq\\_category\\_tid=All&combine=FTCA&=Search](https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions?field_faq_category_tid=All&combine=FTCA&=Search).

50 <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>.

51 <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

52 45 C.F.R. § 46.109(e)-(f).

53 45 C.F.R. § 46.108(a)(3)(iii).

54 45 C.F.R. § 46.110(b)(1)(ii).

An IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.<sup>55</sup> A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB. For example, a research team may deviate from approved recruitment plans in order to increase enrollment, subjects who do not meet criteria approved by the IRB may be enrolled or unapproved advertisements may be utilized for recruitment. The suspension or termination must include the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

**OHRP's Division of Compliance Oversight (DCO) monitors compliance with the Common Rule.** Any active study is subject to a post approval review. Most of these reviews are "not for cause"—routine reviews that have not been prompted by a complaint.

DCO also conducts "for cause" reviews at the request of an IRB or Institutional Official to investigate allegations of non-compliance. Under Title IV of the Public Health Service Act,<sup>56</sup> OHRP has the authority to investigate complaints about human subject protections in HHS-conducted or HHS-funded research, as well as any other research covered by an institution's FWA. Examples of noncompliance identified by OHRP include:

- Failure to receive IRB review and/or approval;
- Failure to provide sufficient information for the IRB to make approval determinations;
- Failure of investigators to obtain informed consent, to document informed consent, to provide a copy of informed consent and/or to include the basic elements of informed consent;
- Failure to conduct continuing review of research;
- Failure to receive IRB review and approval for changes to research; and,
- Failure to report unanticipated problems, noncompliance, suspensions and terminations to the IRB, institutional officials and OHRP.<sup>57</sup>

## *Conflicts of Interest in Research*

In human subjects research, the financial relationships of institutions, investigators and IRB members could conflict with protecting the rights and welfare of human subjects. As described in HHS' 2004 guidance:

HHS recognizes the complexity of the relationships between government, academia, industry and others, and recognizes that these relationships often legitimately include financial relationships. However, to the extent financial interests may affect the rights and welfare of human subjects in research, IRBs, institutions, and investigators need to consider what actions regarding financial interests may be necessary to protect those subjects.<sup>58</sup>

Health centers, familiar with the conflict of interest requirements that apply under the federal grant rules,<sup>59</sup> will recognize similarities in the research grant funding requirements for conflict of interest. Several federal agencies and departments have promulgated rules and/or regulations designed to address potential financial conflicts of interest, including regulations that require all individuals who participate in the design, conduct, or reporting of research funded by the Public Health Service (PHS) agencies to complete training

55 45 C.F.R. 46.113

56 42 U.S.C. § 281.

57 OHRP Compliance Oversight Activities: Determinations of Noncompliance, Types of Determinations, <https://www.hhs.gov/ohrp/compliance-and-reporting/types-of-determinations/index.html>.

58 HHS "Financial Conflict of Interest: HHS Guidance" (2004) available at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html>.

59 Section 330(a)(1) and 330(k)(3)(D) of the PHS Act; 42 C.F.R. § 51c.113 and 42 C.F.R. § 56.114; and 45 C.F.R. § 75.327.

on financial conflicts and to disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict.<sup>60</sup>

- If a health center is the direct recipient of such funds, it should review its conflict of interest policy and procedure to ensure compliance with the PHS regulations.
- If a health center is a subrecipient of such funds or otherwise a partner on such project, it may be asked to certify that it has a policy and to report any known financial conflicts of interest. The definitions and standards for conflicts of interest under research grant regulations differ slightly and should be reviewed in detail to create or update any health center policy and prior to certifying compliance.

## Fraud

A review of recent enforcement actions demonstrates the financial costs related to fraud and misconduct in research, as indicated by these recent headlines:

- Research Institute to Pay \$10 Million to Settle False Claims Act Allegations Related to Mischarging NIH-Sponsored Research Grants<sup>61</sup>
- University to Pay \$13 Million after Self-Disclosing Failure to Ensure Time and Effort Reports were Accurately and Timely Certified<sup>62</sup>
- University Agrees to Pay \$112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct<sup>63</sup>
- Former University Professor Sentenced to Prison for Stealing Cancer Research Funds<sup>64</sup>

Federal fraud, waste and abuse laws and regulations apply to all health center activities, including research activities. For example:

- **False Claims Act:** Permits the imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government for payment of a false claim.<sup>65</sup> A “claim” includes any request or demand for money or property made to the United States or to a contractor, recipient, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Two examples of how the False Claims Act applies to research activities include:
  - **False Statements:** When a health center signs a grant, subaward, or contract or submits ongoing reports, it is assuring the Federal government that it is and will be compliant with the applicable federal requirements. A health center that knows or has reason to know that a research project does not comply with the HHS regulations could face exposure based upon the “false statements” in a grant, subaward, contract or report.
  - **Clinical Research Billing:** Billing research-related procedures and services is complicated because of the various entities responsible for costs related to the study and because

<sup>60</sup> 42 C.F.R. § 50.601 et. seq.

<sup>61</sup> <https://www.justice.gov/opa/pr/scripps-research-institute-pay-10-million-settle-false-claims-act-allegations-related>

<sup>62</sup> <https://www.justice.gov/usao-ndtx/pr/university-north-texas-health-science-center-pay-13-million-settle-claims-related>.

<sup>63</sup> [https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related#:~:text=Duke%20University%20has%20agreed%20to,Environmental%20Protection%20Agency%20\(EPA\)%2C](https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related#:~:text=Duke%20University%20has%20agreed%20to,Environmental%20Protection%20Agency%20(EPA)%2C)

<sup>64</sup> <https://www.justice.gov/usao-edny/pr/former-stony-brook-university-professor-sentenced-prison-stealing-cancer-research-funds>

<sup>65</sup> 31 U.S.C. § 3729(a).

human subjects may receive other non-research procedures and services while participating in research. When a federal research grant fully funds the care provided, billing Medicaid or Medicare could generate False Claims Act liability for duplicative billing to the government. Put simply, services paid for by a research grant should not be billed to another payer. Health centers must ensure that services provided as part of a clinical research are not billed to the patient's insurance.<sup>66</sup> Health centers should be mindful of how patients are informed of and billed for services that might be promised as free in relation to research.<sup>67</sup>

- **Anti-Kickback Statute:** Prohibits the knowing and willful solicitation, receipt, offer or payment of “any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind” in return for or to induce the referral, arrangement or recommendation of Medicare or Medicaid business.<sup>68</sup> Two examples of how the Anti-Kickback Statute applies to research activities include:
  - **Payments to Investigators:** Health centers involved in clinical research should establish systems to ensure that any compensation (in whatever form) received by either the health center or the researcher is justifiable and proportionate to the research activities to be performed. Health centers might also consider establishing compensation limits (either from individual sponsors or for types of compensation) and/or requiring administrative approval for the acceptance of particular types of compensation (e.g., travel, honoraria). While there is no specific regulatory “safe harbor” for clinical research compensation arrangements, it is advisable in negotiating such compensation arrangements to adhere to the key aspects of the Anti-Kickback safe harbors. In particular, compensation should be consistent with fair market value for the research services provided and should not vary based upon volume or value of referrals (or purchased good or services) to the sponsor.<sup>69</sup> Compensation mechanisms, such as enrollment bonuses based on the number of subjects enrolled by the researcher or institution, should be avoided.
  - **Payments to Participants:** While IRBs review potential payments to research subjects, there may be legal risks for health centers beyond those reviewed by the IRB. IRBs examine the context of the research in order to make reasonable judgments about how compensation might affect participation.<sup>70</sup> Payments to research participants can also give rise to potential concerns under the Anti-Kickback Statute and the Beneficiary Inducement Prohibition.<sup>71</sup> Payment considerations tend to fall within the following spectrum of risk, moving from least controversial on the left to more controversial on the right.<sup>72</sup>

66 Centers for Medicare & Medicaid Services. Medicare National Coverage Determinations Manual, Routine Costs in Clinical Trials (Section 310.1) [www.cms.hhs.gov/manuals/downloads/ncd103c1\\_Part4.pdf](http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf).

67 45 C.F.R. § 116(c)(3) When appropriate, the informed consent must include a statement that describes any additional costs to the subject that may result from participation in the research (co-pays and deductibles if billing insurance for routine care).

68 42 U.S.C. § 1320a-7b(b).

69 See 42 C.F.R. § 1001.952.

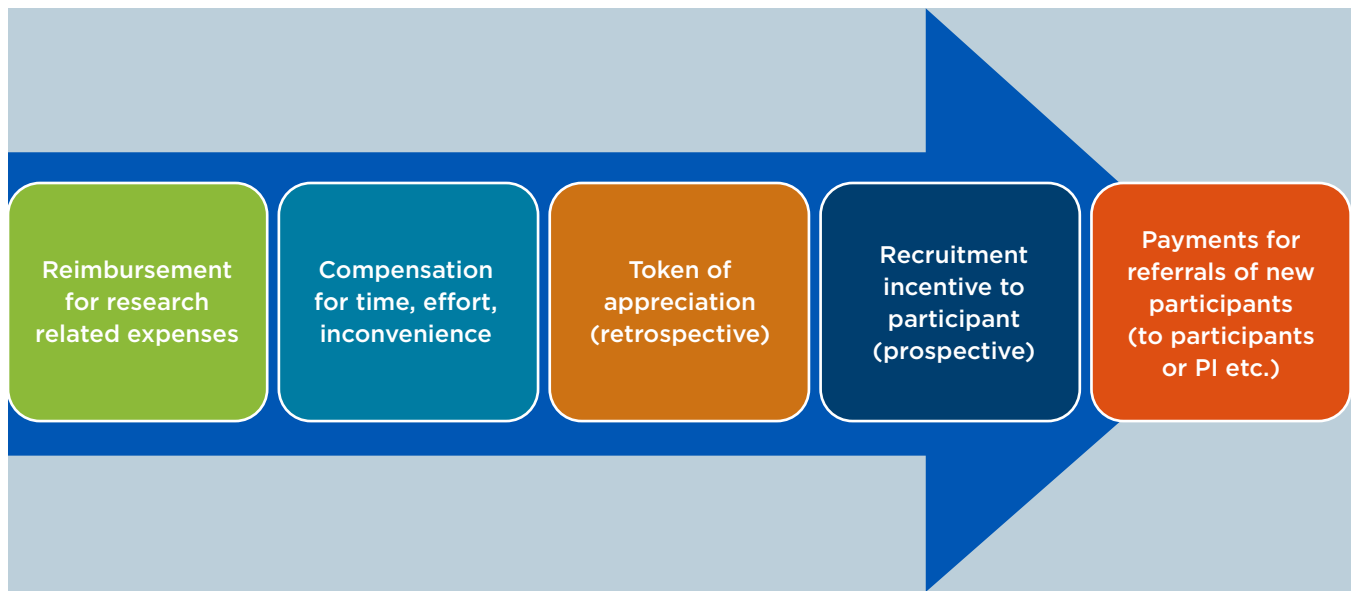
70 See OHRP, “When does compensating subjects undermine informed consent or parental permission?” available at: <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html> (“Information submitted to IRBs should indicate and justify proposed levels and purposes of remuneration, which also should be clearly stated in the accompanying consent forms.”).

71 Section 1128A(a)(5) of the Social Security Act (Beneficiary Inducement) and 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute).

72 Recently, independent, nonprofit research institutions like PCORI have included payment to research subjects as a component of their requests for grant proposals. Health centers involved in PCORI funded research should know that the nonprofit's policy states that it expects grantees to “comply with the US Department of Health and Human Services’ (HHS) Federal Policy for the Protection of Human Subjects, reflected in HHS regulation 45 C.F.R. Part 46.” Whether or not a sponsor like PCORI proposes that a study it funds should involve research subject compensation, a health center may still need to ensure that IRB approval of a proposed payment plan is obtained and that it is comfortable that payments can be disbursed without violating the Anti-Kickback Statute and Beneficiary Inducement Prohibition under the specific circumstances proposed. The precise mechanism and methodology for payment may come under review by the health center before it begins to disburse and track payments.



## Payments to Participants Arrayed Least to Most Controversial



## Research Misconduct

All institutions receiving PHS funding must have written policies and procedures for addressing allegations of research misconduct. Federal policy defines research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”<sup>73</sup> A grant, subcontract or subaward typically binds the health center and its employees to comply with the requirements of the PHS Policies on Research Misconduct and provides details as to how an allegation of research misconduct involving an employee will be handled.<sup>74</sup>

## Malpractice, Insurance and FTCA Considerations

Health centers engaging in clinical research should evaluate potential malpractice liability that could be associated with such activities and whether they have liability protections for such activities. The Public Health Service (“PHS”) Act affords immunity to PHS employees for any claim for damages for personal injury or wrongful death arising out of the PHS employee’s performance of medical, surgical, dental, and related functions *including the conduct of clinical studies or investigation* (emphasis added) within the scope of their employment.<sup>75</sup> Instead of filing a lawsuit, a patient’s exclusive remedy is a claim against the United States under the Federal Tort Claims Act (“FTCA”). The Federally Supported Health Centers Assistance Acts (“FSHCAA”) of 1992 and 1995 extend these immunity protections, including those related to the conduct of clinical studies or investigations, to eligible health centers funded under Section 330 of the PHS Act through an annual deeming process.<sup>76</sup> Once deemed, health centers and their officers, directors, and employees (and certain qualified contractors) have immunity like other PHS employees and patients are required to seek remedies pursuant to the FTCA for actions related to performance of medical, surgical, dental, and related functions including the conduct of clinical studies or investigation.<sup>77</sup>

73 45 C.F.R. Parts 50 and 93. Department of Health and Human Services: Public Health Service Policies on Misconduct; Final Rule. [http://ori.hhs.gov/sites/default/files/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf).

74 A common agreement clause states: Subrecipient must have written policies and procedures for addressing allegations of research misconduct and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

75 42 U.S.C. § 233(a).

76 42 U.S.C. § 233(g).

77 *Id.*

FTCA coverage for clinical studies and investigation does, however, have some limitations. In the FTCA Health Center Policy Manual, BPHC further clarifies that clinical research in the context of patient care “qualifies for FTCA coverage” if it is: (i) within the health center’s approved scope of project; and (ii) within the deemed health center employee’s scope of employment (or the contract for services if such person is an independent contractor).<sup>78</sup> FTCA coverage, with a few specific exceptions, covers only services provided to health center patients, and as such, research involving non-health centers patients is generally not covered by the FTCA.<sup>79</sup> In its discussion of this coverage in the FTCA Policy Manual, BPHC provides the following example:

*A health center provider joins an international clinical research trial that compares two pharmacotherapy strategies to control hypertension using health center patients with the approval of the health center and patients involved. The health center provider and the health center itself would be covered if participation in the study is incident to the medical treatment of the health center’s patients. The health center would not be covered for treatment of non-health center patients as part of the protocol.<sup>80</sup>*

Furthermore, if research activities are conducted “outside” a health center’s scope of project, professional liability insurance should be acquired to cover such activities. Health centers with gap insurance should review their policies and consult with their brokers to determine if such clinical research would be covered by their gap policies or otherwise determine how they will finance any liability risk associated with the activities.

## CONCLUSION

As health centers are approached to participate in research and identify opportunities to build their research capacities, they must balance the legal and compliance risks with the rewards related to research for their organization, their patients and the public. To help assess the opportunities and mitigate the risks, health centers might consider implementing the following strategies:

- Designate an internal team to review research opportunities: This may be a compliance or quality subcommittee with members<sup>81</sup> who can ensure the health center understands the financial, operational and reputational impact of participating in a research opportunity.
- Ensure the health center’s research team:
  - Reviews relevant documentation, including the approved research protocol, any waiver or alternation of the informed consent or privacy requirements.
  - Reviews the IRB’s policies and procedures and communicates research information as required, including reports of unanticipated problems, revisions to the protocols, noncompliance and significant new information.
  - Reviews the health center’s policies and procedures.
  - Completes any required training and education.<sup>82</sup>

<sup>78</sup> HRSA Federal Tort Claims Act (FTCA) Health Center Policy Manual at page 9, *available at* <https://bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftcahpcpolicymanualpdf.pdf> (last accessed January 20, 2021).

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> PCORI and others encourage the inclusion of patients in the decision making of FQHC, including when determining whether to engage in certain research opportunities.

<sup>82</sup> For example, when a health center uses an external IRB, a Reliance Agreement could require the health center to attest to the training offered and taken by a research team. It is not uncommon for universities to have research partners take Responsible Conduct of Research (RCR) training as it is readily available in online module form. RCR training can include: conflict of interest; policies for human subjects research, research with vertebrate animals, and safe lab practices; mentor/mentee responsibilities; collaborative research; peer review; acquisition, sharing, and ownership of data and lab tools; research misconduct; and authorship and publication. In general, universities traditionally have policies that require Principle Investigators to Ensure all members of a study team are appropriately qualified and have met standards for eligibility to conduct research, including completion of human subjects protection training and disclosure of conflict of interest forms. When health centers partner, they can become subject to these standards by contract.

- Select IRBs that meet health center, research institution, and funder needs.
  - Review/revise or develop required and recommended policies and procedures, including:
    - Review and Approval of Research
    - Human Research Protection Program
    - Collaborations and Reliance on External IRB
    - Retention of and Access to Research Data
    - Conflicts of Interest
    - Training for Research Project Personnel
    - Clinical Trial Billing
    - Research Misconduct: Allegations, Investigations, and Reporting

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