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Expanding Decentralized Clinical Trial Options at the UCSF Helen Diller Family Cancer Center

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1. Background
Decentralized clinical trials (DCTs) offer a flexible alternative to traditional site-based clinical research, allowing participants to engage from home and/or local healthcare providers. This model enhances accessibility, efficiency, and participation by utilizing technologies such as telemedicine, wearable devices, and electronic data capture systems. These innovations also alleviate the burden on site staff by streamlining data collection processes. Federal regulatory agencies have increasingly shown support for DCT practices, with the FDA releasing guidance in Fall 2024, *Conducting Trials with Decentralized Elements.*

The UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC), located in San Francisco but serving 25 counties across Northern California, recognizes the challenge many patients face in accessing our main campuses. Travel to our San Francisco locations is often time-consuming, costly, and complicated by tolls, traffic, and limited parking. By studying the DCT model, we aim to expand the number of trials incorporating decentralized elements, offering more options for patients seeking cutting-edge care.

2. Goals
We propose increasing the adoption of DCTs and DCT elements at HDFCCC by piloting selected trials at strategically chosen sites around the San Francisco Bay Area. This pilot program will gather data to ensure successful management of DCTs, taking into consideration the use of technologies, data management, participant uptake, feasibility, and regulatory compliance. The insights gained will inform the scaling of DCTs at HDFCCC, while confirming for our patients, faculty, and staff that the trials are being conducted safely and within regulatory guidelines.

3. Solutions and Methods
To ensure clarity and efficiency, we will define the roles and responsibilities of all stakeholders involved in DCTs. These definitions will set clear expectations, reducing ambiguity and addressing concerns from principal investigators (PIs) and staff. We will also ensure that necessary resources are available and implement a phased approach, beginning with existing network sites who utilize the same instance of Epic as an EMR and gradually expanding to other locations. Additionally, our Protocol Development team will be trained to collaborate with PIs in incorporating DCT elements into new Investigator Initiated Trial protocols. Finally, we will document challenges and considerations related to technology access, compliance, and data security to further inform future DCT participation decisions.

4. Outcomes
The pilot will result in the development of guidelines and best practices for managing DCTs at the HDFCCC. We anticipate increased comfort and interest among faculty in conducting DCTs, as well as a broader acceptance of decentralized trial elements in standard clinical research practice.

5. Learned and Future Directions
This model aims to provide patients with a more flexible clinical trial participation option while enabling UCSF to expand access beyond traditional geographic and socio-economic limitations. As we increase

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DCT activity we envision broader participation in clinical trials, enhancing both patient care and research.