Rewards for Participation

Introduction

Research participants are often remunerated for their participation, and may be reimbursed for expenses, compensated for their time and burden of participation, and offered incentives for their continued engagement. The IRB/EC is responsible for assessing that remuneration is proportionate to the burdens of research participation and that it does not present an undue influence on research participation. There are parallels in non-DCT research that have been discussed extensively in the literature, so the focus of this document will be on aspects of rewards that differ in the DCT context from more traditional research. Note that, like traditional trials, studies vary in the extent of participant burden. A study adding eConsent is not fundamentally different from a study with paper consent. However, studies with a number of expectations for at-home participant responsibility (e.g., wearables, sensors, medication self-administration, at-home surveys, telemedicine, or fully virtual trials) may increase trial burden or even shift the burden from sites to participants. Financial compensation should reflect the time, burden, and expectations of the participant, and the IRB /EC should consider the offer of payment very similarly to that considered in traditional trials.

The nature of rewards in DCTs can, however, extend beyond financial payments. When other types of rewards are introduced, specifically through a digital or mobile platform, those rewards often come in the form of gamification and acquisition of “rewards” for completing a task or entering additional data. The participant can get “caught up” in the game, whether because it is fun (or even compelling) or because of the promise of the reward. Further, participants may not, in the moment, consider whether certain data may be sensitive or private. While IRBs/ECs typically evaluate risks and benefits—and do so in the absence of any consideration of compensation—digital reward systems are often behavioral in nature, and therefore may be both more effective at impacting participant behavior.

Questions for IRBs/ECs to Consider

The IRB/EC should be provided with a summary of how the incentive system is designed, including: what rewards are offered; what requirements must be met in order to receive each reward; and what limits, if any, are in place that restrict the rewards that can be earned (e.g., daily reward limits) and/or restrict the amount of time that participants can dedicate to earning rewards (e.g., maximum hours per day that can be spent while still receiving rewards).

- Do risks to privacy, confidentiality, data storage and transfer change if rewards are given in DCTs? If so, how?
- Will the participant consider the risks and benefits of sharing personal data differently through mobile platforms, tele-visits, or visiting nurses compared to how participants would consider the risks and benefits during in-person visits and via paper forms?
- Will providing rewards in the planned fashion change the willingness of the participant to share their personal data in ways that create undue risk of harm?

- Are there any rewards or features of a reward program that are of particular concern (e.g., because they are engineered to introduce addictive behavioral patterns that have high risk of leading to serious interference with daily life among the target patient population for the trial)?[3]
    - Can the participant engage in choosing the goals of the reward?
    - Are rewards earned through persistent engagement with technology or software?
    - Do rewards accrue evenly or is the schedule of rewards modified by the responses of the participant? In other words, the participant receives X points for answering questions about themselves, but 3X points for answering questions about their sexuality.
    - Are there concerns for persons with addiction or addictive personalities?
    - Are there additional concerns for children who are participating in a DCT trial and are given access to different types of devices?
- Can the promise of the gift of the device and/or software be considered "undue influence," impacting the voluntariness of participation in the study?
- Have any conditions of the reward been considered? For instance, if the gift is earned only at the completion of the trial, will that inappropriately influence the participant's decision to withdraw? Is the reward dependent on sharing specific information?
- Will depreciation affect the value of the device and/or software over the course of the research?
- Is the value of the gift of the device or software proportionate to the time and burden of the research and appropriate for the protocol?
- What provisions have been made if the device is lost during the trial? (See tool for Devices for additional considerations)
- Is there any functionality, information, or other feature that should be removed, disabled, or modified prior to transfer to the participant as a reward?

As in other aspects of DCTs, particular attention to access, transfer, use, disclosure, and safe storage of personal information is necessary.

Specific considerations for participation rewards in DCTs

DCTs are often, but not always, enabled by electronic communications and mobile technologies, and that may be the most salient difference from traditional trials. In the context of "rewards," DCTs offer the possibility of several qualitatively different kinds of rewards.

First, there is *access to the sensor* (e.g., fitness tracker, smartwatch, continuous glucose monitoring system) itself, if the sensor is provisioned for the research rather than provided or brought by the participant. In advance of the research, the study team should decide, and the

[3] IRBs may demand changes to the digital platforms, therefore sponsors should consider whether and how a platform can be modified.

IRB should review, whether and under what conditions the sensor will remain with the participant at the end of the trial, and what to do in the event of sensor loss during the study. *Access to software* drives similar considerations.

Another difference in DCTs is the use of *gamification* as an incentive, which may increase participant engagement. Gamification strategies refer to the use of gaming techniques to motivate ("nudge") certain behaviors. Those behaviors are often positive (e.g., the participant is tasked with an increasing step count each day), but a concern arises when the "game" can only be "won" (or points accrued) if the participant agrees to do or disclose something that they would not have otherwise chosen to do or disclose (and if what they do or disclose is problematic). For example, it would be problematic if the only (or easiest) way to advance or accrue points in the game was by disclosing contact information of friends or certain social activities, information that the person would not have disclosed but for the reward. IRBs should ensure whether gamification is only nudging or renders the clinical trial into a game in itself. Gamification should not mislead participants, who should understand that they are a part of a trial (not a game). Rewards should incentivize people to disclose the information necessary to complete the outcome measures of the research as opposed to "as much information as possible."

Gamification is used throughout the tech industry and is not distinctly different in the DCT context, except that the IRB/EC has a chance to review the testing and rewards. For IRBs/ECs reviewing gamification approaches, there are different risks and vulnerabilities to be considered, in addition to those of the research itself. People with addiction or addictive behaviors may be at greater risk of being "drawn into" the game or app, depending on the circumstances, and addictive behaviors are not typically considered in eligibility criteria. Digital rewards can also have a higher perceived value for the target audience than someone outside of that target audience could reasonably anticipate. Representative community input may be helpful in this evaluation.