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Promoting the participant–researcher partnership

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Over the past few decades, the relationship between researchers and research participants has evolved, due in part to the increased engagement of participants and the increasing volume of research data generated, particularly in genomic studies. Participants have gradually become more engaged in the research enterprise, particularly patient advocacy groups representing hundreds to thousands of prospective participants, by establishing biorepositories and collections of phenotype data, and facilitating partnerships with academia and industry.[1,2] Yet, despite the more proactive role of participants, the individual participant still does not appear to have a close relationship with the researcher, potentially limiting development of a trustful relationship deemed important to the research enterprise.[3] To improve the interaction between researchers and participants throughout the duration of a study and beyond, we propose an online data management system called Participant–Researcher Information Management System (PRIMS).

OVERVIEW OF PRIMS

Modeled after the laboratory and clinical information management systems used in large research and clinical laboratories to enable sample management and tracking, we envision PRIMS to support researchers and participants alike, enabling exchange of information, potentially for multiple studies. A variety of other systems have been developed that facilitate interaction between researchers and participants, including an Internet portal to receive personal disease risks and contact a genetic counselor,[4] and a system to provide secure storage and sharing of large genomic data sets linked to a personal health record.[5] However, to our knowledge, no applications exist to enable the mutual exchange of information between researchers and participants.

Through PRIMS, we aim to establish a multifunctional system to promote such interaction, as well as transparency and responsiveness to the needs and preferences of each group without unduly burdening either. Strengthening the participant–researcher relationship could benefit both parties as well as yield societal benefits. For example, the system may enable researchers to achieve study recruitment goals, an ongoing challenge for clinical trials, possibly in a shorter time frame. A more rapid study recruitment phase may enable extension of the follow-up phase to assess longer-term impacts (if appropriate), or allow researchers to conduct shorter studies, leading to quicker data generation and dissemination to advance the field at a cost savings. The actual research process and all that it entails is likely to be unfamiliar to many, and PRIMS could enhance participants' understanding of how research is conducted by enabling them to follow the step-wise process from enrollment through data collection and interpretation. This enhanced understanding of research can increase trust in the researcher and research enterprise, potentially leading to greater willingness to participate in future studies and reducing attrition rates, as well as serving to recognize the valuable contribution of participants, particularly for minority populations. PRIMS could enhance individual autonomy and respect by invoking a clear and transparent research process, and, when possible, provide personal benefit.

FUNCTION 1: ESTABLISHMENT OF PARTICIPANT PROFILES

A research participant can create a personal profile in one of two ways. In the first approach, the participant has already consented to enroll in a study and provided the required biospecimen. As part of the enrollment process, the study coordinator establishes a participant profile in PRIMS that will automatically assign a unique ID to the participant. The profile will include the contact information of the participant, the study's name and unique study ID (perhaps the same ID assigned by clinicaltrials.gov, if applicable), and study contact information. The participant can later log in to the system to complete the creation of his or her profile with personal information (e.g., family history) and preferences regarding study update notification, access to research results (summary and/or individual), or notifications about new studies. If a participant is concurrently enrolled in multiple studies, each study (and study ID number) would be listed in the participant's profile and be accessible through the site. Alternatively, individuals who are interested in participating in a study but have not yet enrolled can create a profile at any time to obtain a unique name and ID number. Upon enrollment in a study that uses PRIMS, the participant can provide the study coordinator with the ID number to have the new study added to his or her profile.

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FUNCTION 2: SAMPLE TRACKING

PRIMS will enable researchers and participants to track the status of their biospecimen(s) and the progress of the project. Many current biospecimen management systems utilize barcodes to track samples. Likewise, through PRIMS, participant biospecimens will be coded and linked to the participant's unique personal ID and study ID to enable tracking of the sample by both the researcher and the participant. Researchers can also easily post updates about a study's progress and the status of samples.

FUNCTION 3: RETURNING RESULTS

The contentious debate about returning research results to participants has loomed over the entire research enterprise for more than a decade, even more so recently with the large volumes of data generated in studies performing genome-wide analysis. In addition to concerns about potential harms, cost, and time, the distant or nonexistent relationship between participant and researcher, and lack of knowledge about participant preferences also impede the return of individual results. PRIMS would enable online return of summary reports and individual results. The availability of a tool such as PRIMS would enable development of automated calling and classification of results based on an agreed-upon list of conditions (such as was developed for incidental findings from clinical whole-genome or whole-exome sequencing, ref. 6) and/or participant preferences. Alternatively, a classification algorithm could be developed based on a combination of criteria including level of risk, strength of evidence, participant preferences,[7] and availability of clinical interventions.[8] The system could utilize publicly available tools such as the Personalized Genome Project's Genome-Environment Trait Evidence (GET-Evidence) system, enabling automated genome processing and analysis, based on stringent evidence criteria to identify clinically significant genetic variants.[9] Manual curation may be needed for unknown variants of putative deleterious effects. We envision that continuing effort will be required to update databases to ensure that calling and classification is based on the most recent data available. Undoubtedly, the reporting system will be the most complex part of PRIMS to design, likely necessitating pilot testing of multiple versions before achieving an effective automated calling and results reporting system, but such a system may substantially benefit participants.

Participants will have the option to be notified about the availability of summary reports or individual results and to decide which results they wish to access. However, to respect participant autonomy and right not to know, results should not be automatically disclosed, and participants should have the option to request that no alerts be sent regarding availability of summary reports or individual results. Educational tools will be needed to help participants understand the various types of information that could be made available to facilitate informed decision making. For example, a template of the categories or types of risk information available from the study could be developed. A grading system used by groups such as the US Preventive Services Task Force[10] (grades of A, B, C, D, and I, corresponding to substantial, moderate, small, no, and uncertain net benefit, respectively) could also help inform participants' decisions. Disease information, including symptoms, screening/treatments, lifestyle information, and prevention, can be provided, similar to that in the Coriell online portal.[4] All information should be presented at an appropriate reading level to ensure participant understanding.

If results about conditions with no available intervention are to be made available, researchers and institutional review boards may decide that such results should only be returned in-person via a trained professional. However, it may be prudent to provide all participants access to a health professional such as a genetic counselor, perhaps through a mechanism such as a chat room or phone consultation. The expenses of providing such a service may be prohibitive for a research budget; however, they potentially could be provided as a shared resource for a department.

FUNCTION 4: MISCELLANEOUS BENEFITS

We anticipate that PRIMS could provide other benefits as well, including enabling rapid and convenient access to study-specific information for both prospective and enrolled participants. Specifically, PRIMS could be used to update participants about changes to the study or any new interpretation of their individual research results. PRIMS could also provide information about related studies, based on the participant's preferences, and serve as a relatively inexpensive recruiting tool for researchers.

CONCLUSION

Through PRIMS, we aim to strengthen the researcher–participant relationship by increasing transparency of the research process, enabling mutual exchange of information, and increasing understanding and potential benefit to both parties. Individuals without computer access may not benefit from PRIMS, although they should not be restricted from enrolling. Alternative approaches could be arranged, such as setting up a computer kiosk in a convenient location to provide participants access to PRIMS or communicating information about the study, including results, by mail or phone. As with any new system, working out the details will be challenging and complex, and despite the best intentions, unintended consequences of such a transparent system may arise (i.e., participants may become concerned and withdraw). With this first iteration of PRIMS, we hope to motivate further discussion on how best to address the concerns of multiple stakeholders, respect research participants, and advance research.

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DISCLOSURE

The authors declare no conflict of interest.

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