

Table 2. **Rapid Cycle Evaluation of Study Implementation**

	Problems	Consequences	Solutions
Recruitment	1. Slow response time from recruitment materials 2. Labor intensive 3. Underwhelming graphic design in recruitment materials 4. Recruitment limited to Geisinger participant (pt) population	1. Pts aged out of eligibility 1. Unused consenting visit slots 2. Less staff availability for visits 3. Recipients doubted authenticity of materials 3. Recruitment materials easy to overlook 4. Depleted pool of potentially eligible pts	1. Started making recruitment calls before postcards were returned 1. Removed return postcard from mailings 2. Outsourced printing and mailing 2. Outsourced non-responder recruitment calls 3. Utilized Geisinger's Marketing & Communications department for ads 4. Placed flyers in the community 4. Added advertisements (social media, news media, newsletters) 4. Added referrals from participants 4. Added community outreach events
Enrollment	1. Staff time was divided between recruitment and enrollment and other study activities 2. Inefficient informed consenting process 3. Interested pts unwilling/unable to travel to available locations	1. Fluctuating monthly enrollment totals 2. Individual sessions limited number of pts enrolled per day 2. No-shows and cancellations impacted the number of pts enrolled per day 2. Consenter fatigue 3. Interested pts could not be scheduled for enrollment visit	1. Hired, cross-trained, and utilized staff from other departments 2. Group consenting sessions 2. Accounted for no-shows and cancellations by opening additional appointment slots 3. Secured additional enrollment locations for pt convenience and contacted pts again
Protocol and Procedures Fidelity	1. A staff member formatted an appointment sheet incorrectly 2. Photocopier not available at most visit sites required pts to sign two copies of the ICF 3. Paperwork (inclusion form, ICF, gift card confirmation, phlebotomy form, and	Protocol deviations: 1. Printed appointment information was inaccurate, and pts completed wrong visit types (one pt was consented twice and one pt had a blood draw before signing consent) 2. Pts only signed one copy of ICF and took it	1. Staff was trained on how to correctly format appointment sheets 1. Assigned appointment sheet formatting to a specific staff member 2. Implemented audits checking for unsigned or missing ICFs during visits 3. Utilized folders for each pt to organize paperwork at visits

	baseline survey) was challenging to keep organized at visits	home, which resulted in missing paperwork PHI breach: 3. In two instances, pts took other pts paperwork home requiring reports to IRB and Privacy Office	
Participant Experience	1. Inconsistent turnaround time for returning PET-CT scan results 2. Utilized 22 different enrollment sites, each with unique challenges	1. Five participants complained 1. Pts reported stress or anxiety when calling to inquire about PET-CT scan results 2. Site limitations included: a. Poor parking b. Lack of privacy c. Lack of signage to visit area d. Lack of operational management at non-clinic sites	1. Added primary care investigators to the study to return non-cancerous PET-CT results, requiring study oncologists to only return suspicious findings 2. Problem locations were no longer used, or processes were modified a. Detailed parking instructions were provided during scheduling and reminder calls b. Altered visit setup to accommodate for more privacy and safety for pts c. Designed portable study signage for use at all sites d. Assumed more responsibility at sites that lacked operational management