The Clinical Trials Management Benefits of Implementing a Global Materials Protocol

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Background

- The Tumor Vaccine Group (TVG) at the University of Washington is a translational research group focused on immune therapies
- Staff challenges:
  - Limited resources
  - Strict budgets
  - Time constraints
- Study modifications are one of the most time consuming responsibilities faced by TVG staff and the Fred Hutchinson/UW Consortium Institutional Review Board (FHCRC IRB)
- TVG studies involve numerous identical patient-related documents **(Figure 1)**
- The FHCRC IRB mandates:
  - Review of any information given to potential patients
  - All changes to the patient-related documents must be pre-approved
- **Old Process:** Each document was approved separately under each study **(Figure 2A)**
- Changes to any of the patient-related documents = separate study modifications to be submitted to the FHCRC IRB for each study
- To establish a best practice that improved FHCRC IRB approval time and TVG staff productivity, we initiated a "Global Materials Protocol" (GMP)
- **New Process**: The GMP contains documents used for recruitment, outreach, and patient information that are general and used in all studies **(Figure 2B)**
- **Hypothesis:** A streamlined submission process would result in decreased FHCRC IRB review and approval time, and improved TVG staff productivity

Methods

- Initially contacted the Institutional FHCRC IRB to assess the feasibility of establishing this process
- GMP Application:
  - Generalized all GMP documents
  - Completed new FHCRC IRB application
  - Submitted for FHCRC IRB approval
  - Once approved, submitted modifications to each study linking it to the GMP protocol
- After the GMP was in place for 1 year, we retrospectively compared the time required to modify a Breast Cancer Brochure (BC)
- Compared the time involved using the new process (GMP) **(Figure 2B)** vs old process **(Figure 2A)**
  - Compile the study modification by TVG staff (8 hours)
  - FHCRC IRB turn-around time from review to final approval (5 days)
  - FHCRC IRB to return the documents to TVG staff (2 days)

Patient-Related Study Documents

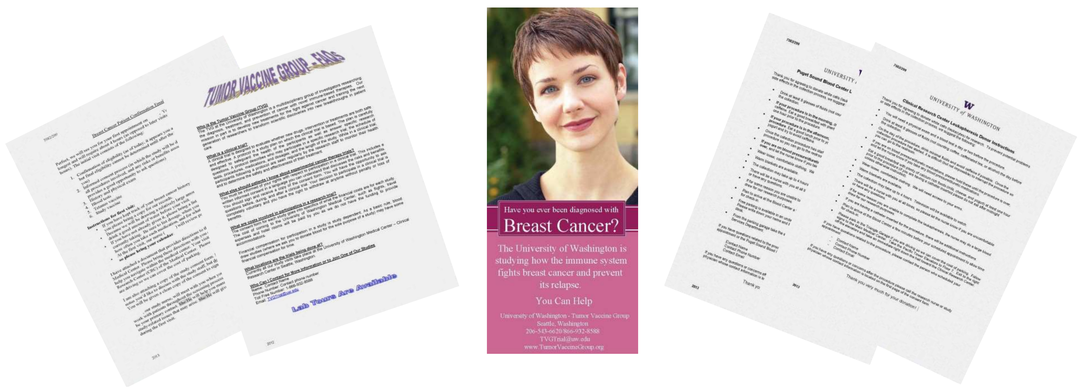

Figure 1: Examples of Patient-Related Study Documents. Shows examples of the patient-related study documents that are used for recruitment, outreach, and patient information (i.e. disease specific recruitment brochures, initial information packets, lodging/transportation information)

Process Comparison

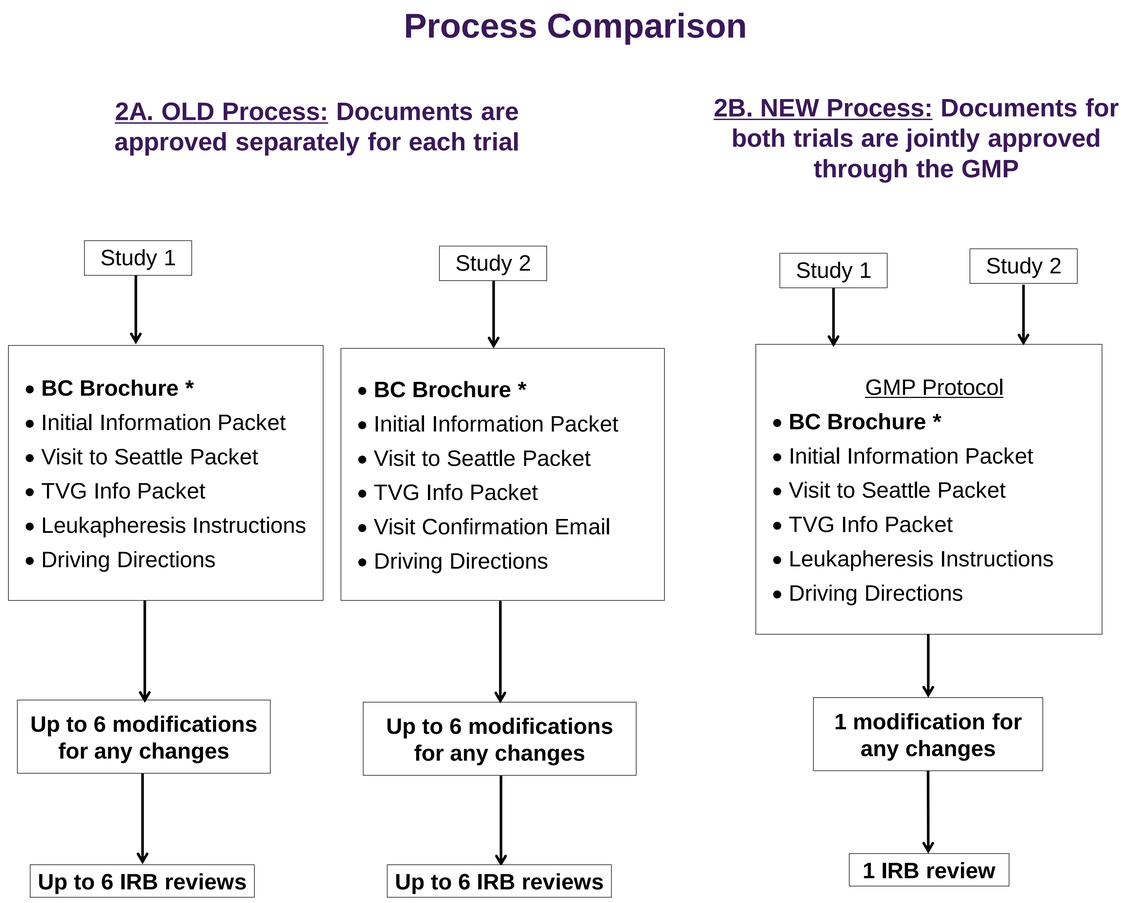

Figure 2. Comparison between old and new process. Shows and compares the steps involved for a document to be modified using the old process and the new process

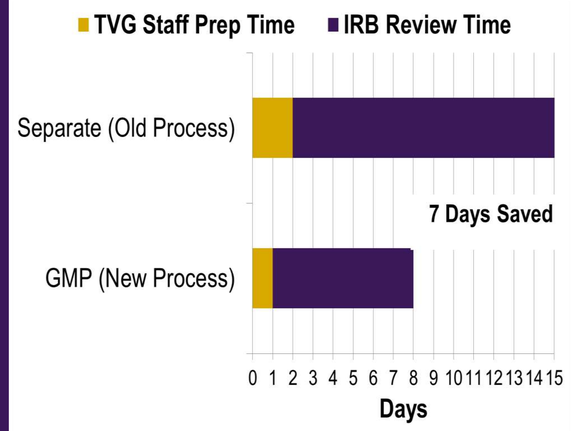

Figure 3: Use of GMP decreases the time needed to approve a modification: Shows the number of days needed by TVG Staff and FHCRC IRB to modify just the BC brochure using the old vs new process

Results

- GMP resulted in a **50% decrease (8 vs 16)** hours on average of TVG staff time
- GMP resulted in a **50% decrease (7 vs 14)** working days for the FHCRC IRB to review and approve the study modification

Conclusions

- Implementation of a protocol containing patient related documents for global use streamlined the submission process which resulted in decreased FHCRC IRB review and approval time, and improved TVG staff productivity
- Time saved by both the TVG staff and the FHCRC IRB could potentially lead to monetary savings; a critical factor in investigator-initiated trials conducted with limited staff and resources
- Development and implementation of novel processes such as a GMP is essential to effective clinical trial management

Acknowledgements

- Mary L. Disis, MD – Founder of TVG
- Lupe G. Salazar, MD – Clinical Core Director
- Clinical Core Team – Responsible for submission of modifications

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