
Plan Overview

A Data Management Plan created using DMPTool

Title: “Caring for Patients while Recruiting for Research”: A Mixed Methods Protocol for Constructing a Professional Identity of Physician-Researchers in Industry-Sponsored Clinical Trials

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Project abstract:

This is a translational science research project that seeks to understand processes contributing to the inefficiency and failure in traditional clinical research. The aim of this project is to understand how physician-researchers participating in clinical trials that are funded by pharmaceutical, medical device, and biotechnology manufacturers define their self-identity, and how the components of their identity contribute to their responsibilities to care for and to recruit their patients. In two phases, this study will use a sequential explanatory mixed methods design to collect, connect, and interpret data about the physician-researcher identity. The quantitative data will be collected for extreme cases sampling in Phase 1. Subsequently, the qualitative results will be used to provide a more in-depth comparison of each investigator case in Phase 2. The aim of this study is to understand how physician-researchers participating in industry-sponsored clinical trials define their self-identity, and how the components of their identity contribute to their responsibilities to care for patients as a physician and to recruit patients in contribution to science.

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“Caring for Patients while Recruiting for Research”: A Mixed Methods Protocol for Constructing a Professional Identity of Physician-Researchers in Industry-Sponsored Clinical Trials

Data Collection

What data will you collect or create?

Three types of data will be collected -- survey data, interview data, and documents.

The initial study phase will collect quantitative survey data based on the Physician Orientation Profile (POP) questionnaire, a tool for measuring how physician-researchers approach their patients and the clinical trial they are participating in as investigators (Taylor & Kelner, 1987). The adapted POP questionnaire includes two parts. The first collects demographic information and information about professional activities in both closed question and open text formats. The second part includes 45 binary response questions aligned to a therapist-experimenter continuum.

Qualitative data will be collected using a semi-structured interview protocol. Audio recordings will be taken of the interviews. The interviews will be directly transcribed and the interview scripts and analytic memos will be added to the database. Code books from the thematic analysis of the interviews will be created and added to the study database. Additionally, if follow-up interviews are performed, they will be similarly transcribed and added to the database.

Publicly available documents will be collected to triangulate the data in the investigator cases. Data will be gathered from ClinicalTrials.gov, professional society websites (if publicly available without membership), published trial reports from PubMed, and institutional/practice websites. Code books from the content analysis of the collected documents will be created and added to the study database.

How will the data be collected or created?

Data Collection Tools

The POP questionnaire will be recreated in electronic format using REDCap™ electronic data capture tools hosted at Children's National Medical Center and accessed via The George Washington University server. The Clinical and Translational Science Institute at Children's National (CTSI-CN) is supported through the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) Program, grant UL1TR001876 and KL2TR001877. The CTSA program is led by the NIH's National Center for Advancing Translational Sciences (NCATS).

REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap has the capability to export the collected data to Microsoft Excel and SPSS, the software programs that will be used in this study for analysis.

The questionnaires will be built and managed by the student investigator on the secure, HIPAA compliant, web-based application using the online designer. The database build will be verified by the study investigator by downloading and reviewing the data dictionary. At least one round of usability testing of the survey will be completed by 2-5 people not associated with the research study. Participants will then access the survey using a public link to the customized REDCap survey page.

Transcription of the audio interviews will be completed by the student investigator using software for audio segmenting, labeling, and transcription software. Transcripts will be uploaded to qualitative software on the local system for analysis. During the qualitative phase analysis, a codebook will be developed.

Version Control

Versioning of files will be controlled through the following naming system:

[data type]_[data name]_[YYYY-MM-DD]_v[xx.yy]

- where *[data type]* describes the *ExportData, Protocol, ICF, DataDictionary, InterviewGuide, CaseBook, etc.*
- where *[data name]* describes the file such as *POP1, POP2, Case4Caring1, Case4Science2, Qual1, Quant2, etc.*
- where *YYYY-MM-DD* is the four digit year, two digit month, and two digit day the file is created
- where *'xx'* is the sequential number of major revision and *'yy'* is the number of times the file is modified

Documentation and Metadata

What documentation and metadata will accompany the data?

Each transcript (both clean and coded) and audio recording will be uploaded to the participant study record in REDCap and maintained with the participant case. The final codebook, analytic memos, and field notes will be uploaded to the File Repository in REDCap.

Ethics and Legal Compliance

How will you manage any ethical issues?

Institutional Review Board Oversight

The study was determined to be research that is exempt from IRB review under DHHS regulatory, category 2. The study was administratively reviewed by The George Washington University, Office of Human Research, ohrirb@gwu.edu, 202-994-2715. The IRB study number is NCR191792 and the approval date is 19 December 2019.

Informed Consent Process

This study waives documentation of consent (electronic or verbal consent). In the informed consent process, an electronic informed consent process will be utilized where the participant will view consent form online in electronic format on a computer and/or personal mobile device. The IRB Stamped/Approved PDF Consent Form will be uploaded into REDCap for participants to download and review. The study participant will be able to download and acknowledge that the document was read. The study participant must agree to the following statement before confirming eligibility to participate:

- I do not have any questions about the research study, and I do not need to review the research with a study team member

If the participant answers "False" to any question, the survey will end. The participant may return to the consent form by accessing the public link again. If the participant answers "True" to the document review questions, the page will remain active and the participant may continue to verify eligibility to participate in the study. The study participant must complete all required fields for the consent form to be validated in REDCap. Without validation in REDCap, the system will not allow the participant to advance to the data collection phase of the study. Additional consent will be required for participation in Phase 2 of the study for the qualitative interviews. The consent form will be delivered via email to the selected cases after agreement to continue in Phase 2 of the research but prior to the interview. The consent forms will be reviewed during the

beginning of the interview and participants will provide verbal agreement to continue participation in the study. Confidentiality and Privacy

There are three primary risks associated with this work: breach of privacy; breach of confidentiality; and the psycho-social risk due to the interview process and the stress of participating in a research study. Steps will be taken to mitigate these risks including the use of GW's private secured servers. Only the research team members and the peer auditor will have access to the study data, including the participant email address.

The following personal and demographic information will be collected from each participant:

- Name
- Age
- Email
- Race / ethnicity
- Sex
- Department / Division
- State

A participant ID is automatically assigned by the REDCap system when a participant signs up with an email address. The email address the participant enters on the consent form will be associated with the participant Record ID. This email address is where the participant will receive correspondence about the study, including links for the follow-up study surveys.

The participant email address is used as a login to complete the remaining survey instruments. If the participant is selected as an exemplar case for the qualitative phase of the study, this email address will be used to invite the participant to be interviewed. Therefore, the email address is associated with the participant study record. The link is maintained within REDCap.

The participant name is never collected in Phase 1 of the study for the online questionnaires. During Phase 2, the participant will be referred by his/her name during the course of the interview and this will be recorded via audio. However, in the study report, an alias will be assigned to the cases and the participant's name will not be associated with the data in the study report.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

Permission to adapt and to use the Physician Orientation Profile questionnaire has been received from Merrijoy Kelner, Ph.D., co-author on the development and study of the Physician Orientation Profile.

Storage and Backup

How will the data be stored and backed up during the research?

Quantitative study data will be collected and managed using REDCap electronic data capture tools hosted at Children's National Medical Center. The questionnaires will be built and managed by the student investigator on the secure, HIPAA compliant, web-based application. All data will be stored on the secure hosted server. Each transcript (both clean and coded) and audio recording will be uploaded to the participant study record in REDCap and maintained with the participant case. The final code book, analytic memos, and field notes will be uploaded to the File Repository in REDCap.

Additionally, all study data will be hosted on the GWU IT-managed OneDrive. Back-up copies of data will be made at regular intervals for storage on external media and secured in a locked safe in the student investigator's office.

How will you manage access and security?

Only the study team will have access to the participant name for Phase 1 and associated study record ID. The Principal Investigator will have access to data stored in the REDCap system as part of the study team.

Only the student investigator will have access to the OneDrive data and the back-up media.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All data will be retained for up to 5 years following completion of the study. Participants may elect to have data destroyed after completion of the study.

What is the long-term preservation plan for the dataset?

Participants may elect to have data destroyed after completion of the study. After 5 years, all portable media containing recordings will be destroyed before discarding the physical media. They will be documented as not recoverable. All recordings saved to an institution-based server will be deleted from the server and temporary files and recycle bin expunged.

Data Sharing

How will you share the data?

Data will be de-identified and, after completion of this study, the email addresses will be deleted from all study records, creating an anonymous dataset for future research. Then, the quantitative data may be made available for re-use. Data may be made available for use after the completion of this research project.

Due to ethics and privacy issues associated with the personal, sensitive nature of the qualitative data, data will not be shared with users outside of the research team.

Are any restrictions on data sharing required?

Exclusive use of the data is needed to support the student researcher's dissertation project. Following completion of the dissertation project, secondary use of the quantitative

research data may be requested. A data share agreement should be put into place prior to sharing of data.

Responsibilities and Resources

Who will be responsible for data management?

The student researcher, Romiya Glover Barry, will be responsible for data management of this project including reviewing, revising, and implementing the data management plan.

What resources will you require to deliver your plan?

Training has been completed for access to the REDCap data capture and management system. When the study is approved by IRB, the student investigator will complete the process to have the study website activated as "live". The software for transcription and network analysis has been downloaded by the student investigator. The software licenses for qualitative data coding (NVivo) and statistical analysis (SPSS) will be purchased by the student after IRB approval as the licenses have time limits on use.