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TITLE: Management of Suicide-Related Events during Deployment

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14. ABSTRACT The broad objective of this project is to provide Army leaders, behavioral health providers and chaplains with targeted, practical, and scientifically-informed guidelines and decision aids on how to respond to suicide-related events during deployment. The study is being conducted in three stages. Stage 1 consists of interviews and focus groups with previously deployed behavioral health providers, chaplains, and unit leaders, as well as Service Members with documented suicide-related events during their deployment. In Stage 2, we will conduct a web-based survey of behavioral health providers, chaplains, and leaders in order to determine the types of decisions made in relation to suicide-related events; identify the methods of decision making for each subgroup in relation to these events; and summarize lessons learned from the outcomes of these decisions. In Stage 3, the qualitative and quantitative data will be synthesized and reported to the Expert Advisory Panel in order to develop guidelines and decision aids for use by providers, leaders and chaplains. Over the past year, our efforts have focused on Stage 1 of the study. We have gained regulatory approvals from the appropriate institutions, developed survey instruments, trained interviewers and coders, administered pilot interviews, and begun subject recruitment and enrollment.					
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Introduction

Suicide has historically ranked as the second leading cause of death in the United States military.¹ While the relationship between deployment and suicide is not yet clearly understood, recent data indicate that suicide in the Army is highest during deployment.² Not much is known about how three types of suicide-related events, (1) suicides, (2) suicide-related behaviors (defined here as: (a) serious suicide ideation with a plan and intent to die; (b) suicide attempts; (c) suicidal behavior that stops short of an attempt (e.g., interrupted attempts)), and (3) suicide-related evacuations, are handled in deployed settings. Furthermore, not much is known about 1) the impact of these decisions on deployed Service Members who are in the suicidal Service Member's unit; 2) whether the decision-making process affects suicidality in the unit; and 3) the impact of suicide-related events on the military personnel involved in decision-making surrounding the suicidal behavior. To date, there are no standardized and systematic procedures within the DoD for the handling of suicide-related events that occur during deployment, nor is there a military-specific empirical base from which to develop these procedures. The broad objective of this project is to provide military leaders, military behavioral health providers (BHPs) and chaplains with a series of targeted, practical, and scientifically-informed guidelines and decision aids for how to best address and respond to suicide-related events during the time of their deployment. In the current project, a mixed methods approach is used to develop these guidelines and decision aids. Stage 1 of the research plan utilizes qualitative methods with the following data sources: (1) confidential interviews with a representative sample of previously deployed behavioral health providers, chaplains, and leaders (Stage 1A); (2) confidential focus groups with a diverse sample of behavioral health providers, chaplains, and leaders (Stage 1B); and (3) confidential interviews with a representative sample of Service Members (Stage 1C) with documented suicide-related events during their deployment. The purpose of Stage 1 data collection is to characterize the most common types of decisions made during the time of deployment pertaining to suicide-related events as well as the possible impact. Stage 2 of the research plan involves designing and administering a comprehensive, anonymous, and confidential survey to a diverse sample of behavioral health providers, chaplains and leaders that will be informed by Stage 1 A, B and C findings. The purpose of the survey is to evaluate the attitudes, opinions, and rationale associated with the most common types of decisions made by behavioral health providers, chaplains, and leaders to address suicide-related evacuations, suicide-related behaviors, and suicide deaths. Stage 3 of the research focuses on the use of the qualitative and quantitative data as the basis of discussion during consensus meetings attended by expert suicidologists, military healthcare specialists, chaplaincy, stakeholders, and military leadership. The data on experiences and lessons learned by various helping professionals and military leaders during their time of deployment combined with the formal review and discussion of this data during the consensus meetings allows for the development of a practical and evidence-informed product for the Army's suicide prevention program. In addition to reports detailing the findings, the study deliverables include a series of clear and feasible "best practices" decision-making guides pertaining to suicide-related events occurring during deployment. These decision aids/guidelines take into consideration the unique needs of military behavioral health providers, chaplains, and leaders in the Army. Best practice guidelines or decision aids produced as a result of this study serve to promote an evidence-informed and standardized manner to handle suicide-related events in the Army during the critical period of deployment.

Body

This project is a collaborative effort among multiple Principal Investigators (PIs) from the University of Pennsylvania (UPenn; Dr. Gregory Brown), the Uniformed Services University of the Health Sciences (USUHS; Dr. Marjan Holloway), and the Columbia University/New York State Psychiatric Institute (CU/NYSPI ; Dr. Barbara Stanley, corresponding PI). The study PIs maintain regular weekly communication via email and conference calls in order to provide oversight for the daily functions of the project and to make timely progress on the stated objectives.

During Year 1, extensive work was conducted to secure regulatory approvals for study implementation, to take appropriate steps to prepare for study enrollment and data collection and to conduct pilot interviews. Adhering to this project's Statement of Work (SOW), the first half of the reporting period was devoted to setting up the study subawards and to interviewing, hiring and training qualified study personnel; contacting members of the Expert Advisory Panel to inform them of study progress and their responsibilities; and elaborating on the study design for this project. At each of the three sites, a Research Coordinator was selected and research support staff was hired to assist with site-specific study tasks. All staff members completed required trainings and became actively involved with study tasks and objectives. In order to ensure regular communication between sites and to ensure steady progress on study goals, a second weekly conference call was initiated at the start of the reporting period and convened regularly throughout the year for the study staff members across the three sites. Also, as appropriate, additional conference calls took place to discuss study-related matters, including development of study interviews and preparing the Institutional Review Board (IRB) applications. Furthermore, study staff worked collaboratively to develop study forms and interview questions, create a database and prepare the necessary regulatory binders.

Early in the reporting period, the study PIs developed a strategy to most efficiently obtain the necessary regulatory approvals based on discussions with each other as well as communication with their site's IRBs and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections. These discussions led to the decision to prepare one IRB application for Stages 1A and 1B (the confidential interviews and focus groups with military leaders, chaplains and behavioral health providers) and a separate application for Stage 1C (the confidential interviews with Service Members with a history of a suicide-related event during deployment). The rationale for this decision was that Stage 1C will require approval from the IRB at Walter Reed National Military Medical Center (WRNMMC), which historically takes many months to obtain. By splitting the Stage 1 studies into two separate applications, the non-clinical portion (e.g. interviews with military leaders, behavioral health providers and chaplains) could be approved quickly while we waited for approval for the clinical portion of the study (e.g., Service Members with a history of a suicide-related event during deployment). Furthermore, a strategy was developed for the submission of Study 1 (Stages 1A and 1B) to further expedite the approval process, where the application would first be submitted to the USUHS IRB and then the approved protocol would be submitted to the UPenn and the CU/NYSPI IRBs and finally to HRPO for final approval. Despite our best efforts to expedite the approval process for Study 1, it took a little over three months to obtain approval from USUHS IRB, followed by another month for approval from UPenn and two months for approval from CU/NYSPI (in part due to the government shutdown). During the review by HRPO, modifications were requested which contributed to additional delays in final IRB approval receipts.

Given these significant delays in obtaining regulatory approval, the confidential interviews and focus groups could not be conducted in the third and fourth quarters, as was initially proposed in our Statement of Work. However, as delineated in the Key Research Accomplishments section, we have focused our efforts on ensuring that the framework is in place for both Studies 1 and 2. Recruitment for Study 1 has begun and we plan to begin conducting interviews early in the next reporting period. We have trained several staff members to conduct the interviews, ensuring that they can be scheduled quickly and efficiently to make up for the time lost in obtaining regulatory approval. We plan to focus on completing the confidential interviews and beginning the focus groups for Study 1 during the next quarter, as well as proceeding with regulatory approval for Study 2. Further, transcription and coding for Study 1 will begin as soon as the first interview is complete during the next quarter.

Key Research Accomplishments

For the first year reporting period, here is a listing of all activities performed by the three study PIs across the three study sites:

Personnel, Training and Cross-Site Communication

1. Hired and Trained Staff at Each Site

Over the past year, the three sites have recruited a strong research team dedicated to accomplishing study goals. Staff members across all three sites have completed the required IRB-related trainings (e.g., CITI) and have been oriented to the objectives of the study.

At the CU/NYSPI site, Dr. Sadia Chaudhury was hired as the site's Research Coordinator (working under the supervision of the site PI, Dr. Barbara Stanley). Her responsibilities include coordinating the site's scientific activities, developing qualitative and quantitative survey instruments, as well as monitoring project timelines and progress on site tasks. In addition, Emily Biggs, a Master's level Research Assistant is assisting with site-specific study activities.

At the University of Pennsylvania, Dr. Abby Adler was selected as the site's Research Coordinator (working under the supervision of the site PI, Dr. Gregory Brown). Her responsibilities include coordinating the site's scientific activities, conducting the coding of interviews and qualitative analyses, and monitoring project timelines and progress on site tasks. In addition, Ashley Mahler, a Master's level research staff member with expertise in regulatory board documentation, and Guy Weissinger, a Master's level research staff member with extensive experience conducting clinical assessments and interviews for research, were hired to provide part-time research support. Drs. Fran Barg and Shimrit Keddem have also been appointed to provide training and consultation on qualitative analysis. Mr. Robert Wheeler was also added to the research staff to assist with IRB coordination and reporting requirements among the 3 sites.

At USUHS, Dr. Jay Carreno served as the site's Research Coordinator (under the supervision of Dr. Marjan Holloway). Her responsibilities included coordinating the site's scientific activities, developing qualitative and quantitative survey instruments, as well as monitoring project timelines and progress on study tasks. Lauren Matthews, a bachelor's level Research Assistant and military spouse was hired to assist with site-specific study tasks. Finally, Kanchana Perera, a Master's level research staff member and military spouse was hired to provide assistance with data management and analysis. In December 2013, Dr. Carreno left her position to serve as a Captain in the U.S. Army. Dr. Holloway has designated other lab research personnel to provide part-time assistance on the project and in the upcoming month, their roles and responsibilities on the project will be more clearly outlined. In addition, two Navy doctoral students in Clinical Psychology have been providing their services to the study in kind.

2. Established Communication across Study Sites – Held Weekly Conference Calls

To facilitate communication across sites and ensure study progress on both study-specific and site-specific tasks, two weekly conference calls were established at the beginning of the reporting period. During the Study PI Coordination Calls, the three project Principal Investigators, Drs. Brown, Holloway and Stanley and the Co-Investigator, Dr. Barg, as well as supporting staff from all three sites were present to collaborate on study-related activities, monitor progress on study-specific and site-specific tasks/deadlines, and to problem solve study-related challenges. During the second weekly call, the Research Working Group Calls, the Research Coordinators at each site, along with other study staff, met to discuss site-specific progress on tasks and to work on specific weekly goals delineated during the PI Coordination Calls. Furthermore, throughout the reporting period, additional conference calls took place to develop the interview questions for Study 1 and prepare materials for regulatory approval.

3. Notified and Contacted Members of Expert Panel

Dr. Holloway, on behalf of all PIs contacted members of the Expert Advisory Panel to notify them that the project had been funded, project activity had begun, and that their continued support was vital for the success of this study. Further, members of the panel were advised that they would be contacted in the near future to assist with research tasks to ensure that study goals are met. The following individuals were contacted, all of whom reaffirmed both their willingness to serve as members of the expert panel and their

commitment to the project: Lanny Berman, Ph.D., ABPP; Stephen V. Bowles, Ph.D., ABPP; John Bradley, M.D.; Russell B. Carr, M.D.; Charles C. Engel, M.D., MPH; David A. Jobes, Ph.D., ABPP; Chris Martin, LCDR; Kim Ruocco, MSW; Gary H. Wynn, M.D.; Richard McKeon, Ph.D., MPH; and Craig Bryan, PsyD .

4. Participated in Training on Qualitative Research and Analysis

During the reporting period, two trainings were provided to study staff on qualitative research and analysis. On January 28, 2013, Dr. Fran Barg provided a training session on the conceptual overview of qualitative methods at UPenn. Dr. Brown and several members of his staff were in attendance. A CD of this training was disseminated to the USUHS and CU/NYSPI sites and staff at those sites reviewed the CD to familiarize themselves with the basic principles of qualitative analysis. On July 19, 2013, the three PIs and study staff from all three sites met at the University of Pennsylvania for a first team meeting. This provided the first opportunity for the entire study team to meet in person. During this one-day meeting, Dr. Shimrit Keddem, an expert in qualitative research, provided training in qualitative research and reviewed the usage of NVivo software to conduct qualitative analyses. The agenda of the meeting is provided in Appendix A.

5. Presented to the Review and Analysis (R&A) Group for Task Area W3 (Deployment)

On February 7, 2013, Dr. Holloway along with Dr. Brown (Dr. Stanley was handling a patient crisis and could not be available) presented this study via conference call to the R&A group. They received helpful comments and feedback from COL Castro and other attendees on the aims, methodology, and implementation plans. The group emphasized the Army focus of this funded study and also provided guidance on how to possibly seek other sources of funding for extending this effort to other branches of the armed services. In addition, COL Castro recommended that the focus of the study should be expanded to include both deployed and garrison settings. While funding does not permit a full scale study of garrison settings, we have added a specific question to the Study 1 interview to evaluate potential differences in how suicide-related events are managed in deployed and garrison settings. If important differences are found, additional funding may be sought to more fully study garrison settings.

Study 1: Regulatory Approval Process, Study Design, and Recruitment

1. Clarified Institutional Review Board Processes for Study 1

The PIs participated in face-to-face, phone, and/or email communication with representatives from the IRBs at USUHS, UPenn, CU/NYSPI, and HRPO. The purpose of this communication was to determine the most efficient manner in submitting and gaining regulatory approvals for the conduct of Study 1, which includes Stage 1A (confidential interviews with behavioral health providers, chaplains and leaders) and Stage 1B (focus groups with behavioral health providers, chaplains and leaders) of the project. Based on this communication, it was determined that the Study 1 application should be submitted to the USUHS IRB first, then to CU/NYSPI and UPenn IRBs simultaneously and finally to HRPO.

2. Prepared IRB Documents for Submission to USUHS IRB

All three sites were actively involved in preparing the application for Study 1 to the USUHS IRB. As part of the application, the protocol, consent forms, recruitment flyers and interview questions were developed by the PIs and study staff members. Dr. Holloway and Dr. Carreno were in contact with the USUHS IRB throughout the preparatory process, and several changes were made to the protocol in order to expedite the regulatory approval process.

3. Developed Interview Questions for Study 1

The PIs and study staff members met regularly to generate questions for the Study 1 interviews to be conducted with behavioral health providers, chaplains, and military leaders. Dr. Fran Barg, a qualitative analyst, was integrally involved during this process given her expertise in qualitative research methodology.

4. Submitted IRB Application to USUHS IRB and Obtained Institutional Approval

The Study 1 protocol was submitted to the USUHS IRB through IRBNet on April 29, 2013. Full approval was obtained on August 5, 2013.

5. Submitted IRB application to UPenn IRB and Obtained Institutional Approval

After receiving approval from USUHS IRB on August 5, 2013, the study application was submitted to Penn IRB on August 11, 2013. The application was reviewed and approved on September 11, 2013.

6. Submitted IRB Application to CU/NYSPI IRB and Obtained Institutional Approval

After receiving approval from USUHS IRB on August 5, 2013, the study application was submitted to the CU/NYSPI IRB on August 11, 2013. At first review, CU/NYSPI IRB recommended a deferral of review for the study to USUHS and initiated communication with USUHS IRB to complete the necessary paperwork. However, due to the government shutdown this process was delayed. Ultimately, Dr. Stanley requested that her site IRB conduct an independent review of the protocol in order to expedite the process of approval. The protocol was reviewed on October 9th and was approved pending minor revisions. The requested revisions were submitted on October 9th and the official approval from NYSPI was received on October 15, 2013.

7. Obtained Regulatory Approval from HRPO for All Sites

The Study 1 application was submitted to HRPO for regulatory approval on August 13, 2013. Dr. Susie Stubbs provided an initial review on behalf of HRPO and made recommendations for necessary changes. Dr. Holloway participated in a call with Dr. Stubbs in order to introduce her to the study and answer the posed questions. The revisions were made and the revised protocol was submitted for review to the IRBs at USUHS, UPenn and NYSPI. Approval notices for all three sites were forwarded to HRPO on 11/4/13. Final approval from HRPO for USUHS was received on 11/12/13. UPenn and CU/NYSPI received final HRPO approval on 12/3/13.

8. Established Recruitment Strategy for Study 1

The PIs developed the following recruitment strategies in order to obtain a representative sample of military leaders, chaplains and behavioral health providers in an efficient manner:

- a. The USUHS team generated and regularly updated a list of individuals in positions of management within the Army behavioral health, chaplaincy, and leadership. This list has been used to target specific supervisors and individuals in the chain of command who can disseminate study-related information to others within their command. Dr. Holloway met with Chaplain Chris Martin at the USUHS site to discuss recruitment strategies for Army Chaplains. Dr. Holloway, on behalf of all study PIs, has also been in contact with the DoD Suicide Prevention Office in order to inform them of the progress being made on the study. In addition, most recently, Dr. Holloway, on behalf of all study PIs, has reached out to the newly appointed Suicide Prevention Program Manager for the United States Army in order to disseminate information about this study and to request for her assistance.
- b. The Study 1 interview includes a question which directly asks for any possible referrals of colleagues who may be appropriate for this research. IRB approved recruitment emails have been prepared for each of the three subgroups so that research staff can approach these referrals about the study.
- c. Recruitment flyers have been created and approved by the USUHS IRB. They have been posted throughout the USUHS campus to increase awareness about the study.

9. Developed Study Forms, Database and Regulatory Binders for Study 1

In addition to the interview questions for Study 1, a demographic questionnaire was developed and piloted. A database to track recruitment, screening and enrollment of study participants was created. Regulatory binders were also created for Study 1.

10. Completed Pilot Interviews for Study 1

Three pilot interviews were conducted with three goals in mind: 1) to train research staff in the conduct of the interviews; 2) to obtain feedback about the interview questions and the overall process; and 3) to allow for further discussion and refinement of the confidential interview questions. Two military behavioral health providers and one chaplain agreed to complete these pilot interviews. The piloting has indicated that the length of the interview is appropriate (about 60-75 minutes), that the questions posed are relevant to the study objectives and deliverables, and that each person has offered a number of unique

lessons learned through the course of the interview. Based on the piloting process, the interview was shortened and refined.

11. Trained Staff on Study 1 Interview

Six staff members (Dr. Jaime Carreno (USUHS), Dr. Sadia Chaudhury (NYSPI), Guy Weissinger (Penn), Marcus VanSickle (Navy Doctoral Student at USUHS), Katheryn Ryan (Research Assistant at USUHS) and Katheryn Holloway (Research Assistant at USUHS) have been trained in the conduct of the confidential interviews. Having several people trained on the administration of the interview allows for maximum flexibility in terms of scheduling the interviews.

12. Prepared Qualitative Coding Database

Drs. Shimrit Keddem and Abby Adler worked together to develop a coding database for the Study 1 interviews. Themes of interest, or “nodes,” will be identified and later refined based on discussion with the PIs and study staff. A database log was created to track changes made to the shared database to ensure the integrity of the coded data.

13. Planned for Transcription of De-Identified Interviews

The Study 1 interview script was amended to inform the research participant at the beginning that the interviewer would avoid using his or her name throughout the interview to maintain confidentiality on the audio recording. In addition, research staff who conduct the interviews were trained on when to begin audio recording in order to ensure that the recordings are de-identified. The PIs discussed and agreed upon a plan for transcription of recorded interviews which will happen at the USUHS site. Research staff who will be responsible for transcription of interviews were identified. Dr. Keddem developed a set of Standard Operating Procedures for transcription and coding procedures.

14. Recruited and Enrolled Subjects for Study 1

Dr. Holloway utilized the list of contacts generated (see Item 8 above) and e-mailed 20 individuals to inform them of the study. Response has been overwhelmingly positive. Study staff have screened and scheduled interested and eligible research participants. The first interviews will take place in the beginning of the next reporting period.

Study 2: Regulatory Approval Process and Study Design.

1. Clarified Institutional Review Board Processes for Study 2

The PIs participated in face-to-face, phone, and/or email communication with representatives from 1) Walter Reed National Military Medical Center (WRNMMC), 2) the IRB at USUHS, 3) the IRB at CU/NYSPI, 4) the IRB at UPenn, and 5) the HRPO at the USAMRMC Office of Research Protections in order to determine the most efficient manner in submitting and gaining regulatory approvals for the conduct of Study 2, which includes Stage 1C (confidential interviews with Service Members who experienced a suicide-related event during deployment). Based on this communication, it was determined that the plan of action for the regulatory process for Study 2 will be as follows: submit the application first to the Walter Reed National Military Medical Center (WRNMMC) IRB first, then to the USUHS, CU/NYSPI and UPenn IRBs simultaneously and finally to HRPO.

2. Prepared IRB Documents for Study 2 for Submission to WRNMMC

The PIs and study staff worked on completing various required IRB documents for submission to WRNMMC IRB. DoD, WRNMMC and USUHS regulations were reviewed and several necessary documents have been prepared, including the protocol, letter of support, impact statements, consent form, and CRADA. We plan to submit the application for IRB approval during the next reporting period.

3. Developed Interview Questions for Study 2

The PIs and study staff members have met regularly to develop the questions for the interviews with Service Members. Dr. Fran Barg, a qualitative analyst, has been integrally involved during this process given her expertise in qualitative research methodology.

4. Identified Additional Questionnaires to be used for Study 2 Data Collection

The PIs discussed the potential merits of adding the Deployment Risk and Resilience Inventory (DRRI-2)³ to the interview in order to better understand the contextual risk and resilience factors present while the Service Member experienced a suicide-related event during deployment. The DRRI-2 is a widely used instrument with 17 distinct subscales that assess deployment-related risk and resilience factors among war veterans in a standardized manner. The Principal Investigators reviewed each module and identified seven modules to be administered as part of the Study 2 assessment battery (Combat Experiences, Post-Battle Experiences, Support from Family and Friends, Unit Support, Relationships during Deployment, Life and Family Concerns, and Family Events) in order to obtain salient information while minimizing burden on research participants.

5. Established Recruitment Strategy for Study 2

The PIs discussed and agreed upon the following recruitment strategy for Study 2: Service Members with a history of a suicide-related event during deployment will be recruited from an inpatient unit on WRNMMC. A brief study description and screening form were created by study staff to facilitate recruitment. The study description will be provided to inpatient staff to inform them of the study's eligibility criteria. The screening form will be given to patients by inpatient staff. Patients who may potentially be eligible for the study based on their responses to the screening questions will be asked by inpatient staff if they would like to be contacted by a member of the research team. If the patient expresses interest, a member of the research team will discuss the study and proceed with the enrollment process. The study description and screening form will be submitted for IRB approval along with the rest of the IRB application during the next reporting period.

Reportable Outcomes

*Brown, G., Ghahramanlou-Holloway, M., Stanley, B. (2013, February). Management of suicide-related events during deployment. Invited presentation for the Review and Analysis (R&A) Group, W3 Deployment Task Area, Frederick, MD.

*Alphabetically listed PIs

Conclusion

There are no study findings to report at this time. The first year has heavily focused on hiring study personnel, developing study measures, elaborating study design, creation of the study database and regulatory binders, and most significantly, obtaining regulatory approvals. Study 1 recruitment began at the end of the last quarter and we plan to have results to share in the next annual report for this study.

The early study conclusions have been derived from the pilot interviews conducted in preparation for the start of Study 1 recruitment. Based on feedback provided by two military behavioral health providers and a chaplain, it was determined that experiences managing a suicide-related event during deployment differ based on location, context and who is involved. There is also concern about overwhelmingly negative perceptions of behavioral health providers both by those in command and by Service Members. We also concluded the study interview was an appropriate length, questions were clear and targeted, and that responses provided information salient to study aims.

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Appendix A



Aaron T. Beck Psychopathology Research Center
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**Deployment Study
Meeting Agenda**
Friday, July 19th, 2013
10:30am – 4:30pm
3535 Market Street, Room 3076
Philadelphia, PA

10:30 – 11:00am	Welcome and Introductions Discussion of study issues: - o Study 1 responsibilities (consenting, interviewing, transcribing, coding) - o Study logo and name - o Demographics forms - o Study 2 interview questions
11:00am – 12:00pm	Brief Overview of NVivo 10 (Abby)
12:00 – 1:30pm	Lunch at White Dog Café (3420 Sansom Street)
1:30 – 4:30pm	NVivo Training (Shimrit) o Please bring a laptop (not a MAC) with NVivo10 trial version (for the individual researcher) installed: http://www.qsrinternational.com/products_nvivo_free-trial-software.aspx