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Health Care Systems Research Collaboratory

Ethics and Regulatory Core

UH2 Project: A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity *Trauma Survivors Outcomes and Support* (TSOS)

Douglas Zatzick, MD

April 20, 2015
2:15pm – 3:15pm EST

Attendees:

☒ Monique Anderson, MD *Duke Clinical Research Institute*	☒ Jeff Love *University of Washington*	☐ Galia Siegel, PhD *NIH / NIMH*
☒ Josie Briggs, MD *NIH / NCCIH*	☒ Jonathan McCall, MS *Duke Clinical Research Institute*	☒ Irene Stith-Coleman, PhD *OHRP*
☒ Elaine Collier, MD *NIH / NCATS*	☒ Jerry Menikoff, MD, JD *OHRP*	☒ Jeremy Sugarman, MD, MPH, MA *Johns Hopkins University*
☒ Doyanne Darnell, PhD, MA *University of Washington*	☒ Cathy Meyers, MD *NIH / NCCIH*	☒ Erik Van Eaton, MD *University of Washington*
☒ Leslie Derr, PhD *NIH / OD*	☐ Jeri Miller, PhD *NIH / NINR*	☒ Wendy Weber, MD, PhD, MPH *NIH / NCCIH*
☒ Brett Hagman, PhD *NIH / NIAAA*	☐ Andrew Narva, MD *NIH / NIDDK*	☒ Kevin Weinfurt, PhD *Duke Clinical Research Institute*
☒ Catherine Hammack, JD, MA *Duke Clinical Research Institute*	☒ Pearl O'Rourke, MD *Partners Healthcare*	☐ Barbara Wells, PhD *NIH / NHLBI*
☒ Adrian Hernandez, MD, MHS *Duke Clinical Research Institute*	☐ Jane Pearson, PhD *NIH / NIMH*	☒ Doug Zatzick, MD *University of Washington*
☐ Cheri Janning, BSN, RN, MS *Duke Translational Medicine Institute*	☒ Ivor Pritchard, PhD *OHRP*	
☒ Gregory J. Jurkovich, MD, FCAS *Denver Health Medical Center*	☒ Tammy Reece, MS, PMP, CCRA *Duke Clinical Research Institute*	
☒ Julie Kaneshiro, MA *OHRP*	☐ Marcel Salive, MD, MPH *NIH / NIA*	

These minutes were circulated to all attendees for two rounds of review and they reflect all corrections that were received.

Agenda Item	Discussion	Action Item
Brief review of *A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity* (Trauma Survivors Outcomes and Support (TSOS))	• Dr. Zatzick gave an overview of the TSOS project. o The study's overarching goal is to develop and implement a large scale, cluster randomized pragmatic clinical trial demonstration project that directly informs national trauma care system policy targeting injured patients at risk of Posttraumatic Stress Disorder (PTSD) and related comorbidity. o The study will involve twenty-four (24) sites, each a level one trauma center. o It will implement a stepped wedge, cluster randomized design. o The control group will receive enhanced usual care, while the intervention group will received stepped collaborative care. o The intervention is the amalgam of standard of care, usual care, and best practices. In other words, each element is an acceptable, desirable, evidence-based method; it is the *integration*—the package—that is the novel intervention. ▪ Specifically, the first step is the practitioner's empathic engagement at the bedside in an attempt to establish a therapeutic alliance with the patient; then the practitioner will coordinate care from the trauma center to primary care and the community. The second step is to respond to PTSD and other comorbidities with the combination of various mechanisms, all of which are standard of care, usual care, and best practices. ▪ This package of interventions is ideal, but not often used in real-world.	

IRB status and approval	○ Outcome assessments will occur at three- (3), six- (6), and twelve- (12) month intervals. ○ In response to questions regarding contamination, Dr. Zatzick explained that the project team will train a specific work unit within a hospital. ▪ It was suggested that the team could use historical data as a baseline for comparison with outcome changes. However, Dr. Zatzick explained that anything longitudinal would be very hard to document. ▪ The TSOS team and attendees acknowledged that the stepped-wedge design might very well have a community effect; indeed, the fact that the team is doing this study may itself impact care. • Dr. Zatzick explained that the American College of Surgeons' Committee on Trauma (ACS/COT) oversees trauma centers, but does not have an IRB. The University of Washington does not have centralized IRB capacity. Dr. Zatzick's team has approached Western IRB (WIRB) as the consolidated IRB of record. Only five (5) sites were willing to cede to WIRB. Additionally, there are four (4) individual sites approved through their own institutions, eleven (11) being processed, and four (4) awaiting submission. TSOS has been approved as meeting the minimal risk criteria by WIRB (UH3 protocol) and the University of Washington IRB (UH2 pilot). • Additional information is included in the Summary Document *attached* hereto.	
Risk *Does the project meet regulatory criteria for being considered minimal risk?*	• TSOS has been approved as minimal risk by WIRB and the University of Washington IRB. • In response to questions of whether or not the pilot study was informative with respect to risk, Dr. Zatzick explained that the pilot study was informative with respect to IT and administrative logistics but did not change any of the team's baseline assumptions about the study constituting minimal risk.	

Consent *Planned processes for relevant subjects*	• Dr. Zatzick explained that a waiver of consent will be used to examine EHRs for at risk population; those at risk will then be approached for participation and consent. Patients are not asked to consent for the initial screening, but they are asked at the time of randomization regardless of the arm to which they are assigned. • Dr. Zatzick explained that trauma registries are kept in trauma care centers as standard practice, and the TSOS team will be obtaining the data therefrom. o Within these data, there will be people who did not consent both because (i) they actually declined, and (ii) they were never asked. • In response to questions about assessing capacity and competency to consent, Dr. Zatzick explained that they will employ an initial pre-approach screening (including Glasgow Coma Scale (patients with a score of 15/15) plus an abbreviated version of the Mini–Mental State Examination). The informed consent process will be facilitated by a nurse or social worker with clinical experience. o Additionally, they will assess willingness to participate longitudinally by asking a participation question ("Had I known in advance what participating would be like for me I still would have agreed to participate") at varying intervals; thus far, most people respond with *true* or *mostly true*. • The attendees raised the concern that many patients will be prisoners at time of trauma or become prisoners as a result of the trauma. In response to questions regarding vulnerable subjects approval for those patients who will become prisoners, Dr. Zatzick explained that although this is a major issue, his team anticipates that less than 5% of their population will be incarcerated post-enrollment. Further, they will not approach those who are obviously "prisoners." Furthermore, if the team discovers that a patient was indeed incarcerated at a later time, they will not approach them for follow-up. o It was suggested that Dr. Zatzick's team may want to consider getting approval for the follow-up of prisoners, because if they lose many patients to incarceration, they will lose trial integrity. [Post call note: Of 5,803 trauma center patients included in their previous multisite trauma center investigation, 119 or approximately 2% were	

	incarcerated at the time of approach for the study (see attached Zatzick et al., Addiction 2014 Figure 1). In addition, in an ongoing TSOS study team longitudinal investigation, 2/104 patients were incarcerated at the time of study follow-up; also, incarcerated patients frequently exit jail settings within study follow-up windows. Given only potential limited gains in incarcerated patient accrual, and the likelihood that obtaining approvals to enroll prisoners in the research may delay IRB approvals across the 24 sites, the study team would prefer not to include prisoners as currently articulated in the approved WIRB UH3 protocol.]	
Privacy *Including HIPAA*	• The project will use a HIPAA waiver for initial screenings. *No questions or concerns raised.*	
Monitoring and Oversight	• The NIMH DSMB will review the protocol mid-June, and if necessary, modifications will be integrated into the final protocol and then submitted to the IRBs for review/approval. • Dr. Zatzick explained that they anticipated sharing the following outcomes with the DSMB: adverse events (medication side effects, death (which is not unlikely in a trauma setting)), suicidality, loss to follow up, and demographics.	
Issues beyond this project *Regulatory and ethics concerns raised by the project, if any*	• There was a brief discussion of the step-wedge design issue as a larger question, as well as secular changes in different interventions based on publicity of the trials. In addition, there is a need for additional guidance for data monitoring for these kinds of trials.	
Other	• Dr. Zatzick explained the TSOS team hopes to release their data at the end of the trial. The Collaboratory is based on data sharing; thus, the central papers that will come out should have a data set that is available to share with others.	[NIH will follow up with staff at FDA to determine whether the proposed work

	• [Post call note: A question was raised about whether FDA has jurisdiction in this study since part of it involves the use of approved psychotropic agents.]	is exempt from IND regulations.]

A Policy Relevant US Trauma Care System Pragmatic Trial for PTSD and Comorbidity:
Trauma Survivors Outcomes and Support (TSOS: UH2MH106338)
NIH Health Care Systems Research Collaboratory Regulatory Discussion April 20, 2015, 2:15-3:15pm EDT

1. Participating Institutions and Organizations

Prime Grant Awardee
University of Washington, Seattle WA
Principal Investigator, Douglas Zatzick, MD

Data Coordinating Center
Departments of Psychiatry and Behavioral Sciences and Surgery
Harborview Medical Center/Level I Trauma Center, University of Washington School of Medicine

American College of Surgeons' National Steering/Advisory Committee
Gregory Jurkovich, MD
Ronald Maier, MD
David Hoyt, MD
Avery Nathens, MD
Erik Van Eaton, MD

NIH Program Officers
Jane Pearson, PhD (NIMH)
Brett Hagman, PhD (NIAAA)

NIMH DSMB Liaison
Galia Siegel, PhD

Study Sites
24 US level I trauma centers

2. TSOS Study Synopsis

Objective

The overarching goal of this proposal is to work with the NIH Health Care Systems Research Collaboratory to develop and implement a large scale, cluster randomized pragmatic clinical trial demonstration project that directly informs national trauma care system policy targeting injured patients with presentations of Posttraumatic Stress Disorder (PTSD) and related comorbidity. Each year in the United States (US), over 30 million individuals present to trauma centers, emergency departments, and other acute care medical settings for the treatment of physical injuries. Multiple chronic conditions including enduring PTSD, alcohol and drug use problems, depression and associated suicidal ideation, pain and somatic symptom amplification, and chronic medical conditions (e.g., hypertension, coronary artery disease, diabetes, and pulmonary diseases) are endemic among physical trauma survivors with and without traumatic brain injuries (TBI). Evidence-based, collaborative care/care management treatment models for PTSD and related comorbidities exist. These care management models have the potential to be flexibly implemented in order to prevent the development of chronic PTSD and depressive symptoms, alcohol use problems, and enduring physical disability in survivors of both TBI and non-TBI injuries; care management models may also be effective in mitigating the impact of the acute injury event on symptom exacerbations in the large subpopulation of injury survivors who already carry a substantial pre-injury burden of multiple chronic medical conditions.

Participating facilities

24 US level I trauma centers.

Patient population

960 injured patients with high PTSD symptoms levels. Patients will be identified through a two-step process. Patients identified by an electronic medical record evaluation as being at-risk for high early PTSD symptom levels (i.e., a score of ≥ 3 risk domains positive) will be formally screened for study entry with the patient reported outcome measure, The PTSD Checklist. Formal study cohort definition occurs with the PTSD Checklist; patients scoring ≥ 35 on the PTSD Checklist will be followed in the longitudinal portion of the investigation.

Design overview

The investigation aims to employ a stepped-wedge cluster randomized design. In the stepped wedge design, level I trauma center sites are randomized sequentially to initiate the intervention, thus allowing collapsed within site pre-, post- intervention comparisons as well as between site comparisons. In the UH3 implementation phase, after IRB approval is obtained, each of the 24 trauma center sites will be randomized to one of four waves. All sites will begin with control patient recruitment and each wave is assigned a specific proportion of control and intervention patient recruitment. Wave 1 recruits 8 control and 32 intervention patients, wave 2 recruits 16 control and 24 intervention, wave 3 recruits 24 control and 16 intervention and wave 4 recruits 32 control and 8 intervention patients. The demonstration project aims to recruit 960 patients, 40 at each trauma center site.

Usual care control and intervention conditions

Patients in the control condition will receive enhanced trauma center care as usual. Enhanced trauma center care as usual consists of nurse notification of control patients who screen into the study with high PTSD symptom levels. Patients in the intervention condition will receive a collaborative care intervention targeting PTSD and related comorbidities. The intervention will begin with a one-day workshop training in care management, medication, MI, and CBT elements targeting PTSD and related comorbidity. These workshop trainings will occur on site at each of the 24 level I trauma center sites. The site PTSD champion as well as trauma surgical, nursing, psychiatric, social work, and other allied mental health providers who are already routinely delivering care at each of the sites will be invited to attend the workshop training. After the one-day workshop, the site will receive ongoing decision support tool facilitated supervision from the study team.

Hypotheses

The primary hypothesis is that the intervention group when compared to the control group will demonstrate significant reductions in PTSD symptoms over the course of the year after injury. Secondary hypotheses are that intervention patients when compared to control patients will demonstrate significant reductions in

depressive symptoms, significant reductions in alcohol use problems, and improved post-injury physical function.

Primary outcome
The major outcome variable of interest is the patient reported outcome assessments of PTSD (assessed with the PTSD Checklist).

Secondary outcomes
Secondary patient reported outcomes include alcohol use problems (assessed with the AUDIT), depression (PHQ-9), and physical function (MOS SF-36 PCS). Exploratory analyses of primary and secondary outcomes will examine intervention effects in patients with and without medical and surgical comorbidity (e.g., chronic medical conditions, traumatic brain injury); these data will be obtained from trauma registry derived electronic medical record ICD codes.

Data collection
Outcome analyses will incorporate baseline patient-reported outcome and trauma registry derived EMR data, as well as patient-reported outcome assessment data from the 3-, 6-, and 12-months post-injury patient interviews.

Analyses
All primary statistical analyses will be conducted using intent-to-treat methods. The primary goal of the statistical analyses is to examine and compare trends over time in the symptoms of PTSD. The major test of the intervention effect will be the change in PTSD symptoms from baseline to the 12-month study endpoint. We will also examine changes in PTSD symptoms from baseline to the 3- and 6-month study time points as well as the treatment group by time by interaction for PTSD symptoms over the course of the 12 months after injury. Incorporating a 25% 12-month rate of patient attrition, with each of the 24 trauma center sites recruiting 40 patients into the study, the study is anticipated to have 80% power to detect effect sizes ranging from 0.22 to 0.23.

Study oversight
The investigation is using a consolidated IRB structure. The Western IRB is serving as the IRB of record for the trial; WIRB has approved the study protocol (approval date 3-16-15). Five of the 24 sites will defer individual site IRB to the Western IRB; the remaining 19 sites have elected to review the protocol through local site IRBs. This is an NIH-defined phase 3 clinical trial and will use the NIMH DSMB as the study external DSMB. The NIMH DSMB will monitor the study for data integrity, and safety.

3. Risk Determination

The study team determined that the risks of the study are minimal based upon the observations that follow.

3.1 Confidentiality of non-consented cohort patient subjects
This study will collect de-identified trauma registry data from each trauma center at the end of recruitment for all patients who come in to the trauma center during the time of recruitment but did not consent in to the study. The patients in this list are considered non-consented patient subjects and waivers of HIPAA authorization and of consent have been obtained to access these data. The only risk to these individuals is a slight risk to their confidentiality and has been made not greater in and of themselves than those ordinarily encountered in daily life and/or in routine medical care by way of having the trauma registrar at each site remove all HIPAA identifiers from the dataset prior to transporting it to the data coordinating center.

3.2 Confidentiality of consented patient subjects
Patient subjects who enroll in the study have a slight risk to their confidentiality. These subjects are being asked to answer sensitive questions about their mental and physical health and exposure to trauma, and the answers provided to these questions could have a negative impact if viewed by individuals not part of the study. To offset this risk, all data is being entered into a web-based decision support tool built and secured by the University of Washington data coordinating center and is only accessible to members of the data coordinating center team or a respective site's study team through a password. Both the web server and

database server are maintained and secured by the University of Washington Information Technology Services (UW-ITS). Additionally, site providers will locally store a list of prospective and current subjects on the encrypted site laptop that will be de-identified prior to transmission to the data coordinating center. All device, applications, and databases have undergone the production readiness and security assessment protocol put forth by UW-ITS. Once these consented patient data are downloaded from the decision support tool, all identifiers will be removed and replaced with a subject ID. There will be only one master list connecting identifiers to subject IDs and this master list will only be available to University of Washington data coordinating center staff who have been granted access privileges.

3.3 Patient subject risk to health

Patient subjects assigned to the Usual Care group will experience no risk greater than that they would have as part of their routine care in that the only activity that will occur outside of the routine care offered at a recruiting site is that any distressing scores reported on the PTSD Checklist or Patient Health Questionnaire item 9 on the baseline interview will be reported to their attending nurse so that they can enhance their care with any available resources onsite. Patient subjects assigned to the Intervention group will receive a stepped collaborative care treatment that consists of a combination of care management, resource linkage, elements of psychotherapy, and psychopharmacology as needed. While this intervention is novel in its collaborative model, all of the individual elements and medications that make up the model are treatments already regularly available at a trauma center, therefore the intervention poses no more risk than what normally may be experienced.

3.4 Confidentiality of provider subjects

The only risk to provider subjects taking part in the protocol is a slight risk to their confidentiality. Provider subjects are being asked to answer sensitive questions about both their views on their work environment and their own personal experiences with trauma and exposure to trauma, and the answers provided to these questions could have a negative impact on their work if viewed by colleagues of their workplace. The data coordinating center has offset this risk of confidentiality by designing a web-based survey for provider subjects to complete and will advise that provider subjects that they should only complete these surveys in a private location away from their hospital work site. Access to these data is only available to research staff at the data coordinating center and only if they have a password for accessing the database. Once these data are downloaded from the database, all identifiers will be removed and replaced with a subject ID. There will be only one master list connecting identifiers to subject IDs and this master list will only be available to data coordinating center research staff that has been granted access privileges. No hospital site staff will ever have access to these data in an identified format.

<u>Further Considerations Related to Patient Subject Risks</u>

1) Life Threatening Conditions and Clinical Deterioration: Previous investigations suggest that injured trauma survivors treated in acute care trauma center and emergency department settings may develop life threatening conditions, such as suicidal ideation or intent. Other life threatening conditions may arise as a result of medication administration or acute care surgical/medical procedures, whether administered as part of the patient subject's involvement with the study care manager (e.g., psychotropic medications) or the standard clinical care provided at the site (e.g., follow-up surgical appointments). To minimize this risk, the research group has developed a protocol in which the development of any potential life threatening conditions, including suicidality, identified in either baseline or follow-up interviews, or during the intervention contacts for the intervention group, will be further assessed for severity by the interviewer or the intervention staff (e.g., in the case of possible suicidal ideation, the interviewer or intervention staff will assess whether the patient subject has current suicidal ideation). At baseline during recruitment, any suicidal ideation identified by interviewers with a PHQ-9 item 9 score of ≥ 1 will result in a notification of suicidal ideation to the patient subject's nurse.

If in the course of the baseline interview/evaluation the patient subject is identified as having a self-inflicted injury, the patient subject will be paid for their time, and the patient subject will be excluded from the study and have no further involvement with the study team; the interviewer may also recommend that hospital procedures for the evaluation of self-inflicted injury be initiated. The interviewer will also follow-up with the patient subject's nurse and inform them that the injury was self-inflicted. The UW research coordinator will also be notified of self-inflicted injury exclusions that occur after consent has been obtained.

For 3-, 6-, and 12-month follow-up interviews, both acute and passive levels of life threatening conditions (e.g., suicidality) will be triaged immediately (in less than 24 hours) to the intervention supervision team. The team and/or interviewer will inform the UW research coordinator of the event. In the case of a serious incident (e.g., suicide attempt), a representative from the intervention supervision team will follow-up directly with the patient subject over the phone, and the study PI, to ensure proper care and follow-up occur (e.g., link patient subject with crisis resources or, if life threatening, contact the patient subject's PCP and/or other emergency personnel). A member of the intervention supervision team will be available 24 hours a day by cellphone to receive information regarding acute life threatening conditions.

2) Emotional Distress: The surgical ward/emergency department baseline and follow-up interview may produce discomfort or anxiety secondary to the discussion of trauma related and emotionally laden topics. Questionnaire items assess sensitive topics, including suicidality, substance use, and anxiety and depressive symptomatic distress. To minimize this risk, the study team will employ multiple procedures. The principal investigator and intervention team members will train care managers and research assistants conducting follow-up interviews and administering questionnaires in empathic listening and interviewing skills. Basic principles to be discussed during these trainings include the gradual pacing of interviews, allowing subjects to return to or defer items that are the source of major distress, and when to stop an interview and call the intervention supervision team. The study team will also assess and monitor patient subject reactions to research participation throughout the study.

3) Testing Burden: Patient subjects may experience inconvenience and invasion of privacy from the in-person and telephone interviews. The total anticipated time required for interview participation is between 4-5 hours over the course of the study. To minimize this risk, all attempts will be made to conduct surgical ward/emergency department and telephone follow-up interviews at convenient times. If patient subjects experience fatigue or distress during an interview, they will be allowed to discontinue. All intervention and control group patient subjects will be compensated for their participation in the research interviews.

4) Confidentiality: Patient subjects will be initially approached in their hospital beds/emergency department gurneys and asked to answer potentially sensitive questions about depression, suicide, PTSD, and alcohol and drug consumption. The follow-up questionnaire will also include these types of sensitive questions. This creates a risk that a patient subject's confidentiality will be breached. To offset this, all attempts will be made to make their in-person interviews private (e.g., pull the curtain between beds, conduct interview in another location if patient is mobile). For phone interviews, the study team will always try to arrange for a time when the patient subject can be away from any other individuals, behind a closed door, or in a space that is inaudible to other individuals.

4. Recruitment of patient subjects

4.1 Rationale for waivers of HIPAA authorization and consent
A waiver of HIPAA authorization and waiver of consent have been granted by the Western IRB for the overall study, and each site that is under review has also applied for these waivers. These waivers are necessary for:
1) Screening medical records for potential subjects who are inpatient for a traumatic injury and
2) Transfer of the trauma registry data of non-consented patient subjects who were inpatient during the time of recruitment at each site.
As described in section 3.2, the risk to non-consented patient subjects is no greater than what they normally would experience in that these data will be transmitted to the data coordinating center in de-identified format.

4.2 Consent of patient subjects
Patients who appear to be a good fit for the study will be approached and taken through the consent process and asked to sign both a consent form and a HIPAA authorization form (unless the HIPAA authorization is already written into the consent form). During the consent process, patient subjects will be informed of:
1) Purpose of the study
2) Difference in treatments (usual care vs. intervention) and the randomization of treatment
3) Follow-up interviews
4) Risks and benefits of participating
5) Confidentiality

6) Reasons for breeching confidentiality
7) Alternative options to enrolling
8) Right to withdraw from either the study or medical record access at any time and means by which they can do this
9) Source of funding
10) Certificate of Confidentiality
11) Contact information for questions or complaints
Patient subjects will be given copies of their forms for their own records and later referral.

4.3 Consent of provider subjects
Providers contacted by the University of Washington study team who are interested in participating will be mailed consent forms and a phone call will be scheduled to be taken through the consent process and asked to sign and mail back a signed copy of the consent form. During the consent process, provider subjects will be informed of:
1) Purpose of the study
2) What they will experience
3) Risks and benefits of participating
4) Confidentiality
5) Reasons for breeching confidentiality
6) Alternative options to enrolling
7) Right to withdraw from the study at any time and means by which they can do this
8) Source of funding
9) Contact information for questions or complaints
Provider subjects will not be sent questionnaires until signed consent forms are received in the mail by the University of Washington team.

5. Study Oversight

The trial is being conducted under a cooperative agreement between the NIH and the University of Washington. Because the University of Washington IRB does not currently have the capacity to act as the IRB of record, the Western IRB will act as the IRB of record. This is an NIH-defined phase 3 clinical trial and will use the NIMH DSMB as the study external DSMB. The NIMH DSMB will monitor the study for data integrity, and safety. For further details regarding individual site IRB approvals and WIRB cedes see Table 1 below.

Table 1. Individual Site IRB Status

Site	Cede to WIRB	IRB Status
Baylor		Submitted
Cedars-Sinai		Submitted
Georgia Regents	YES	In Process
Hartford		Pre-Review
Iowa	YES	In Process
LSU		In Re-review
Madison		Yet to be Submitted
North Memorial		Submitted
Ohio State		Submitted
Regions		Submitted
Santa Clara		Approved
Scott & White		Submitted
Scottsdale		Submitted
Strong Memorial		Yet to be Submitted
UC Davis		Reviewed Awaiting Outcome
Wake Forest		Conditionally approved
Wishard		Pre-review
UT Galveston		Submitted
Cincinnati	YES	WIRB In Process
Vermont		Yet to be Submitted
Kentucky Chandler Hospital		Submitted
Inova Fairfax	YES	Processed by WIRB
Jacobi Medical Center	YES	WIRB In Process
UT Southwestern		Conditionally Approved
UCLA Harbor (Wait list)		Yet to be Submitted
Utah (Wait list)		Submitted