Protocol Summary

Protocol Status:	Research - Not HS
Principal Investigator:	**Dunn, John Christopher**
Protocol Title:	Population-based surgical outcomes

Study Number:	202001		
Animal Research:	○ Yes ◉ No	**Phase:**	
Coordinating Protocol Number:		**Storage Code:**	
Blinding Method:		**Project Number:**	20-09833
Research Type:		**Therapeutic Area:**	
Current Enrollments:	0	**Accrual Target:**	
Peds Category:		**Radiation Use:**	
FDA Regulated:	No	**Has IND/IDE:**	No
Emergency Use:	No		

⊟ Protocol Site(s)

	Name	Is Primary
	P and R - William Beaumont Army Medical Center (WBAMC)	Yes

⊟ Protocol Personnel

Principal Investigator:	John Christopher Dunn
Study Contact:	John Christopher Dunn
Co-Investigator:	Daniel William Nelson, DO MAJ
Study Author:	John Christopher Dunn
Associate Investigator:	John Philip Scanaliato, M.D CPT; Joseph Thomas Lanzi Jr, MD LTC; Joshua Tadlock, M.D.; Kayla Regina RIZZO, D.O. CPT; Kyle Jay Klahs, DO CPT; Matthew Eric Wells, Doctor of Osteopathy; Michael Douglas Eckhoff, MD CPT; Michael Mccord Polmear; Oriana Venniese Ellis, MD; Sasha Lynn LIGHTFOOT, DO; Spencer S Schulte, MD; Tyler Clare Nicholson
Team Member:	Arturo Alvarez

William Beaumont Army Medical Center (WBAMC) Determinations

IRB Number:	20-24
IRB of Record:	Yes
Please Select the Type of Review Notification that Must be Sent:	Email with Home Screen Task and Continuing Review
Committee of Record:	--none--
IRB Initial Approval:	
Review Cycle:	
IRB Expiration Date:	
Last Continuing Review Approved:	
Days Prior to IRB Expiration:	
Continuing Review Due:	
Temporary Closed:	No
Risk Assigned:	
Adult Risk Assigned:	
Adult Benefit Assigned:	
Pediatric Risk Assigned:	
Exempt:	No
Subject Approved:	0
Subject Justification:	
Select Categories For Study:	Common Rule - Effective January, 2018
	N/A

Exempt: ☐

☐ Category 1: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ Category 3: i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7). ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: i. The identifiable private information or identifiable biospecimens are publicly available; ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or

service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

- ☐ Category 6: Taste and food quality evaluation and consumer acceptance studies if, (i) wholesome foods without additives are consumed or (ii) if plant or animal raised food products are consumed which are at or below the regulated level found to be safe.
- ☐ Category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8).
- ☐ Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d); ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117; iii. An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Expedited Review Category:

- ☐ N/A
- ☐ Category 1(a): Clinical studies of drugs for which an investigational new drug application is not required
- ☐ Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (healthy non pregnant adults 110lbs or more, no more than 550mL in 8 weeks and no collection more than 2x a week OR other adults and children not exceeding the lesser of 50 ml or 3 ml per kg in an 8 week period and no collection more than 2x a week)
- ☐ Category 3: Prospective collection of biological specimens for research purposes by noninvasive means
- ☐ Category 1(b): Clinical studies of medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling
- ☐ Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing
- ☐ Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
- ☐ Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes
- ☐ Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
- ☐ Category 8(a): continuing review of research where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects.
- ☐ Category 8(b): continuing review of research where no subjects have been enrolled and no additional risks have been identified.

- ☐ Category 8(c): continuing review of research where the remaining research activities are limited to data analysis.
- ☐ Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Continuing Review Expedited Review Category:

- ☐ N/A
- ☐ Category 8(a): Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects
- ☐ Category 8(b): Continuing review of research previously approved by the convened IRB where no subjects have been enrolled and no additional risks have been identified
- ☐ Category 8(c): Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis
- ☐ Category 9: Continuing review of research, not conducted under an IND or IDE where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

Investigational Drug Use:

- ☐ IND use approved under 21 CFR 312
- ☐ IND Exempt as per 21 CFR 312

Investigational Device Use:

- ☐ Non-Significant Risk Device under 21 CFR 812.66
- ☐ Significant Risk Device Use under 21 CFR 812.3(m)
- ☐ IDE Exemption under 21 CFR 812.2 (c)
- ☐ Humanitarian Use Device (HUD)

Documentation of Consent:

- ☐ Written consent in accordance with 45 CFR 46.117/ 21 CFR 50.27
- ☐ Waiver approved under 32 CFR 219.117 (c) 1 or 2/ 21 CFR 56.109 (c)1
- ☐ Partial waiver approved under 32 CFR 219.117 (c) 1 or 2/ 21 CFR 56.109 (c)1
- ☐ Short form-oral presentation approved under 32 CFR 219.117 (b) (2)/ 21 CFR 50.27 (2)

Waiver of Consent:

- ☐ Waiver/alteration approved 32 CFR 219.116 (c)or(d)
- ☐ Partial waiver/alteration approved 32 CFR 219.116 (c)or(d)
- ☐ Emergency research waiver approved under 21 CFR 50.24

HIPAA:

- ☐ No PHI collected, accessed, used or distributed under 45 CFR 164.514
- ☐ HIPAA Authorization for research approved under 45 CFR 164.508 (a) (1)
- ☐ Limited Data Set under HIPAA Privacy Rule
- ☐ Waiver of HIPAA Authorization for Research approved under 45 CFR164.512 (i) (2) (ii)
- ☐ Partial waiver of HIPAA Authorization for Research approved under 45 CFR164.512 (i) (2) (ii)
- ☐ Preparatory to research PHI use approved under 45 CFR 46.164.512 (i) (1) (ii)
- ☐ Use or disclosure of decedents PHI approved under 45 CFR 46.164.512 (i) (1) (iii)

Children Risk Assessment:

- ☐ (DoDI 3216.02, Enc. 3, para 7/45 CFR 46.404/ 21 CFR 50.51): Not greater than minimal risk
- ☐ (DoDI 3216.02, Enc. 3, para 7/45 CFR 46.405/ 21 CFR 50.52): Greater than minimal risk, but prospect of direct benefit to the subject
- ☐ (DoDI 3216.02, Enc. 3, para 7/45 CFR 46.406/ 21 CFR 50.53): Greater than minimal risk, with no prospect of direct benefit to the subject but likely to yield generalizable knowledge about the subject's disorder or condition -

Risk represents a minor increase over minimal risk

- ☐ (DoDI 3216.02, Enc. 3, para 7/45 CFR 46.407/ 21 CFR 50.54): approvable after secretarial review, risk represents more than a minor increase over minimal risk
- ☐ Because the adolescents being enrolled in this study are legally entitled to consent to the treatments and procedures involved in the study, Subpart D of 45 CFR 46 does not apply. Parental consent is not required.

Assent:

- ☐ Assent waived under 45 CFR 46.408/ 32 CFR 219.116/ 21 CFR 50.55 / DoDI 3216.02, Enc. 3,para. 7
- ☐ Assent from some or all under 45 CFR 46.408/ 32 CFR 219.116/ 21 CFR 50.55 / DoDI 3216.02, Enc. 3,para. 7

Parental Permission:

- ☐ One parent signature
- ☐ Two parent signatures
- ☐ Requirement for parental permission waived under 45 CFR 46.408/ 32 CFR 219.116 / 21 CFR 50.55 / DoDI 3216.02, Enc. 3,para. 7

Pregnant Woman/Fetuses/neonates:

- ☐ Inclusion of pregnant women approved under 45 CFR 46.204/DoDI 3216.02, Enc.3, para. 7
- ☐ Inclusion of neonates approved under 45 CFR 46.205/DoDI 3216.02, Enc.3, para. 7
- ☐ Inclusion of placenta/fetal materials approved under 45 CFR 46.206/DoDI 3216.02, Enc.3, para. 7
- ☐ Inclusion of pregnant women/neonate/fetuses approved after Secretarial review under 45 CFR 46.207 /DoDI 3216.02, Enc.3, para. 7

Prisoners:

- ☐ Prisoners - inclusion approved under 45 CFR 46.306 / DoDI 3216.02, Enc.3, para. 7
- ☐ 45 CFR 46.306(a)(2)(i) / DoDI 3216.02, Enc.3, para. 7 Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- ☐ 45 CFR 46.306(a)(2)(ii) / DoDI 3216.02, Enc.3, para. 7 Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- ☐ 45 CFR 46.306(a)(2)(iii) / DoDI 3216.02, Enc.3, para. 7 Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
- ☐ 45 CFR 46.306(a)(2)(iv) / DoDI 3216.02, Enc.3, para. 7 Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- ☐ DoDI 3216.02, Enc. 3,para. 7.b.(2)(a) Epidemiological research with prisoners: The research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. The study poses no more than minimal risk and presents no more than an inconvenience to the prisoner subjects, and prisoners are not the focus of the research.

Surrogate Consent:

- ☐ Use of LAR / Next of Kin, Note: Study must be compliant with 10 USC 980

Problem/Deviation/Non-Compliance:

- ☐ Minor Non-compliance
- ☐ Serious Non-compliance
- ☐ Continuing Non-Compliance
- ☐ Unanticipated Problem
- ☐ Event reportable to ASD(R&E) via Component HQ per 32 CFR 219 and DoDI 3216.02 and FDA per 21 CFR 56

Comments

Master Lay Summary

The Truven Marketscan database is a commercial available database which is comprised of data collected from de-identified encounters from federal and private insurance. This de-identified retrospective, population-based data can

then be analyzed to review trends in specific fields.[1] Internal medicine,[2] orthopaedic surgery,[3] hand surgery,[4] neurosurgery,[5] facial surgery,[6] and oncologic surgery[7] have used this database for demographic and outcome studies. This knowledge empowers clinicians to better guide treatment and educate their patients. On a population level, this data helps improve health system efficiency and reduce cost. The purpose of this protocol is to both identify population demographics within surgical diagnoses and to identify outcomes of surgical procedures.

William Beaumont Army Medical Center (WBAMC) C&T

Comments

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Protocol Details:

Sponsor	No Sponsors have been associated.
Protocol Drug/Biologic/Chemical agents	No Drugs have been associated.
Protocol Devices	No Devices have been associated.
Inclusion Criteria	No Inclusion criteria have been associated.
Exclusion Criteria	No Exclusion criteria have been associated.
Treatment Criteria	No Treatment criteria have been associated.
Workup Criteria	No Workup criteria have been associated.