



NINDS Common Data Element (CDE) Project

Traumatic Brain Injury Version 3.0

Internal Review / Public Review

Digital Technologies Subgroup Materials

Subgroup Summary

Case Report Forms

- Digital Technology Wearables
- Physiology and Big Data



NINDS CDE Project Traumatic Brain Injury Version 3.0 Digital Technologies Subgroup Summary

The NINDS TBI v3.0 Common Data Element (CDE) Digital Technologies Subgroup developed CDEs based on advancements in neuroscientific clinical research.

The Digital Technologies Subgroup focused on algorithmically determined and objective markers. Digital biomarkers are used in TBI to assist in classifying the nature and severity of injury.

The subgroup assessed objective validated instruments from both observational and experimental studies as well as screening tools and rigorous classifiers in pediatric and adult populations. The subgroup expanded their review to include objectively measurable social and environmental markers.

Summary of Recommendations

Subdomain	CRF Name	Classification	Population
Digital Technology	Digital Technology Wearables	Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
Vital Signs and Other Body Measures	Physiology and Big Data	Supplemental – Highly Recommended	Adult; Pediatric

Case Report Forms/CDEs for Future Consideration

Case Report Forms for the Most Common Device Interventions
Transcranial Electrical Stimulation: Transcranial Direct Current Stimulation (tDCS) / Transcranial Alternating Current Stimulation (tADS)
Transcranial Magnetic Stimulation (TMS)
Vagal Nerve Stimulation
Audio-Visual Entrainment
Deep Brain Stimulation
Brain-computer Interface
Electroencephalogram (EEG) Neurofeedback
Ocular CDEs
Addition of ocular CDEs to the Digital Technology Wearables CRF: ocular motility; pupillometry; blink

Digital Technology Wearables (New for TBI)

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:

Visit Name:

1. **What type of wearable was used?
☐ Watch/bracelet ☐ Waist ☐ Ring ☐ Chest ☐ Glasses ☐ Headband ☐ Skin patch
☐ Other, specify:
2. **Wearable brand (research grade is recommended):
☐ ActiGraph/Ametris
☐ Actiwatch
☐ Other, specify:
3. **Wearable model:
4. **What was the duration of recording (days)?
 - a. Average hours per day:

PHYSICAL ACTIVITY METRICS

5. **Average daily step count:
6. Average daily distance traveled: ☐ Miles ☐ Kilometers
7. Average daily calories burned:
8. **Average daily active time (HH:MM):
9. **Average daily vigorous activity time (HH:MM):
10. **Average daily sedentary time (HH:MM):

EXERCISE DATA

11. **Was the wearable being worn during exercise?
☐ Yes ☐ No ☐ Unknown
12. **Exercise type (Choose all that apply):
☐ Walking ☐ Running/jogging ☐ Swimming ☐ Cycling ☐ Gym ☐ Ball sport ☐ Other, specify:
13. **Participant's competition level: ☐ Rec ☐ Club ☐ Scholastic below HS ☐ HS ☐ College ☐ Professional ☐ Military ☐ Other

CARDIOVASCULAR DATA

14. **Average daily resting heart rate (beats per minute):
15. **Average daily real-time heart rate (beats per minute):
16. **VO₂ maximum estimate (ml/kg/min):
17. **Standard deviation of normal-to-normal heart rate intervals (SDNN) [ms]:

Digital Technology Wearables

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- 18. **Root mean square of successive heart rate differences (RMSSD) [ms]:
- 19. Heart rate low-frequency power (LF) [ms²]:
- 20. Heart rate high-frequency power (HF) [ms²]:
- 21. LF/HF ratio (%):
- 22. **Heart rate sampling frequency (Hz):
- 23. **Heart rate mode of detection:
☐ Electrical (e.g., electrocardiogram [ECG]) ☐ Optical (e.g., photoplethysmography) ☐ Other, specify:
- 24. **Average blood pressure over 24 hours (mm Hg; systolic/diastolic):
- 25. Average daytime blood pressure (mm Hg; systolic/diastolic):
- 26. Average nighttime blood pressure (mm Hg; systolic/diastolic):
- 27. **Blood pressure sampling frequency (Hz):

SLEEP TRACKING

- 28. **Average sleep duration (HH:MM):
- 29. Average sleep duration in stage 4 (deep sleep) (HH:MM):
- 30. Sleep efficiency score:

Recorder Signature:

Date:

Digital Technology Wearables CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) is intended for participants using wearable devices in clinical studies.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

Some of the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below, and should be collected if exercise technology studies are performed.

****Element is classified as Supplemental – Highly Recommended**

The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study design(s) and type(s): Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.

The data elements on this CRF Module are part of the NINDS CDE Outcomes and End Points Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- What type of wearable is used? – Choose one.
- Wearable brand – Choose one. A research grade wearable is recommended.
- Wearable model – Enter the wearable model.
- What was the duration of recording (days)? – Enter the number of days of data that were recorded on the participant's wearable device.
- Average hours per day – Enter the average number of hours of data recorded per day.
- Average daily step count – Enter the average number of steps taken by the participant per day.
- Average daily distance traveled – Enter the average distance traveled by the participant per day. Select the unit, either miles or kilometers.
- Average daily calories burned – Enter the average number of calories burned by the participant per day.
- Average daily active time (HH:MM) – Enter the average amount of time in hours and minutes of active time completed by the participant per day. Active time is defined as time spent on physical activity that elevates the participant's heart rate and requires more effort than resting.
- Average daily vigorous activity time (HH:MM) – Enter the average amount of time in hours and minutes of vigorous activity time completed by the participant per day. Vigorous activity time is defined as time spent on physical activity of moderately hard to hard intensity, e.g., running, swimming, biking, and playing ball sports.
- Average daily sedentary time (HH:MM) – Enter the average amount of time in hours and minutes the participant was at rest per day.
- Exercise type – Choose all the types of exercise that apply to the participant during the recording period. Exercise type applies to exercise while wearing digital technology during a clinical study, not exercise related to head trauma exposure.

Digital Technology Wearables CRF Module Instructions

- Participant's competition level – The level of competition related to the sport in which the participant participated.
- Was the wearable being worn during exercise? – Choose one.
- Average daily resting heart rate (beats per minute) – Enter the average daily resting heart rate in beats per minute.
- Average daily real-time heart rate (beats per minute) – Enter the average daily real-time heart rate in beats per minute. The real-time heart rate should be based on continuous measurement, recording both resting and active heart rates throughout the day.
- VO₂ maximum estimate (ml/kg/min) – Enter the VO₂ maximum estimate in milliliters per kilogram per minute, i.e., the highest amount of oxygen the body can use per minute. The protocol should state which method of VO₂ calculation was used.
- Standard deviation of normal-to-normal heart rate intervals (SDNN) – Enter the standard deviation of the interbeat interval of normal sinus beats, measured in milliseconds. Abnormal beats, such as ectopic beats, have been removed.
- Root mean square of successive heart rate differences (RMSSD) – Enter the root mean square of successive differences between normal heartbeats, obtained by first calculating each successive time difference between heartbeats in milliseconds, then each of the values is squared and the result is averaged before the square root of the total is obtained.
- Heart rate low-frequency power (LF) – Enter the absolute power of the low-frequency band (0.04-0.15 Hz), measured in milliseconds squared.
- Heart rate high-frequency power (HF) – Enter the absolute power of the high-frequency band (0.15-0.40 Hz), measured in milliseconds squared.
- LF/HF ratio – Enter the ratio of LF to HF power, which may estimate the ratio between sympathetic nervous system and parasympathetic nervous system activity under controlled conditions, measured as a percentage.
- Heart rate sampling frequency – Enter the numerical value of the heart rate sampling frequency in hertz.
- Heart rate mode of detection – Choose one. If Other, specify chosen, enter the other mode of detection as free text.
- Average blood pressure over 24 hours – Enter the average daily systolic and diastolic blood pressure in millimeters of mercury.
- Average daytime blood pressure – Enter the average daytime systolic and diastolic blood pressure in millimeters of mercury. Daytime is defined as 6AM to 5:59PM.
- Average nighttime blood pressure – Enter the average nighttime systolic and diastolic blood pressure in millimeters of mercury. Daytime is defined as 6PM to 5:59AM.
- Blood pressure sampling frequency – Enter the numerical value of the blood pressure sampling frequency in hertz.
- Average sleep duration (HH:MM) – Enter the average amount of time in hours and minutes the participant was asleep per day.
- Average sleep duration in stage 4 (deep sleep) (HH:MM) – Enter the average amount of time in hours and minutes the participant was in a state of stage 4 deep sleep per day.
- Sleep efficiency score – Typically reported as a percentage or value out of 100 calculated by the technologies' proprietary software algorithm.

REFERENCES

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Digital Technology Wearables CRF Module Instructions

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Esterov D, Pradhan S, Driver S, Whyte J, Bell KR, Barber J, Temkin N, Bombardier CH. The temporal relationship between moderate to vigorous physical activity and secondary conditions during the first year after moderate to severe traumatic brain injury. *Arch Phys Med Rehabil.* 2024;105(3):506–513.

Ramsey J, Driver S, Swank C, Bennett M, Dubiel R. Physical activity intensity of patients with traumatic brain injury during inpatient rehabilitation. *Brain Inj.* 2018;32(12):1518–1524.

Shaffer F, Ginsberg JP. An Overview of Heart Rate Variability Metrics and Norms. *Front Public Health.* 2017 Sep 28;5:258.

Physiology and Big Data (New for TBI)

(Study Name/ID pre-filled)

Site Name:
Participant ID:

Visit Date/Time:

Visit Name:

ACQUIRED SIGNALS

(Metadata related to signals acquired from a monitor and monitoring sites)

1. Photoplethysmography Values Sampling (Choose all that apply):

- ☐ Measured
- a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Finger
 - ☐ Ear
 - ☐ Forehead
 - ☐ Toe
 - ☐ Other, specify:
 - c. Timing:
 - a. Start Date/Time:
 - b. End Date/Time:
- ☐ Digitized
- a. Frequency (Hz):
 - b. Units of measurement:
 - ☐ Arbitrary units (a.u.)
 - ☐ % relative amplitude
 - c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

2. Systemic Oxygen Saturation (SpO2) Values Sampling (% saturation) (Choose all that apply):

- ☐ Measured
- a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Finger
 - ☐ Ear
 - ☐ Forehead
 - ☐ Toe
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Digitized
- a. Frequency (Hz):
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

☐ Secondly derived outside of multiparametric monitor

3. Electrocardiogram (ECG) Values Sampling (mV) (Choose all that apply):

☐ Measured

a. Device Name:

☐ Multiparametric monitor

☐ Other, specify:

b. Body Site:

☐ Lead I

☐ Lead II

☐ Lead III

☐ aVR

☐ aVL

☐ aVF

☐ V1–V6

☐ Other, specify:

c. Timing:

i. Start Date/Time:

ii. End Date/Time:

☐ Digitized

a. Frequency (Hz):

b. Source of data acquisition:

☐ Multiparametric monitor

☐ Directly from device

4. Heart Rate (HR) Values Sampling (Beats per minute) (Choose all that apply):

☐ Measured

a. Device Name:

☐ Multiparametric monitor

☐ Other, specify:

b. Body Site:

☐ Electrocardiogram/Telemetry

☐ Arterial blood pressure

☐ Intracranial pressure

☐ Pulse oximetry

☐ Cerebral Blood Flow velocity

☐ Other, specify:

c. Timing:

i. Start Date/Time:

ii. End Date/Time:

☐ Digitized

a. Frequency (Hz):

b. Source of data acquisition:

☐ Multiparametric monitor

☐ Directly from device

☐ Secondly derived outside of multiparametric monitor from:

☐ Electrocardiogram/Telemetry

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- ☐ Arterial blood pressure
- ☐ Intracranial pressure
- ☐ Pulse oximetry
- ☐ Cerebral Blood Flow velocity
- ☐ Other, specify:

5. Carbon Dioxide Waveform Values Sampling (Choose all that apply):

- ☐ Measured
 - a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Ventilator
 - ☐ Capnography
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Endotracheal tube
 - ☐ Nasal cannula
 - ☐ Tracheostomy
 - ☐ Mask
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Digitized
 - a. Frequency (Hz):
 - b. Units of measurement:
 - ☐ mmHg (millimeters of mercury)
 - ☐ kPa (kilopascals)
 - c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

6. End Tidal Carbon Dioxide (EtCO₂) Values Sampling (Choose all that apply):

- ☐ Measured
 - a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Ventilator
 - ☐ Capnography
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Endotracheal tube
 - ☐ Nasal cannula
 - ☐ Tracheostomy
 - ☐ Mask
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- ☐ Digitized
 - a. Frequency (Hz):
 - b. Units of measurement:
 - ☐ mmHg (millimeters of mercury)
 - ☐ kPa (kilopascals)
 - ☐ % (percent)
 - c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device
 - ☐ Secondarily derived outside of multiparametric monitor

7. Tidal Volume Values Sampling (Choose all that apply):

- ☐ Measured
 - a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Anesthesia machine
 - ☐ Ventilator
 - ☐ Capnography
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Endotracheal tube
 - ☐ Tracheostomy
 - ☐ Non-invasive mask
 - ☐ Nasal cannula
 - ☐ Mouthpiece
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Digitized
 - a. Frequency (Hz):
 - b. Units of measurement:
 - ☐ mL (milliliters; standard for tidal volume)
 - ☐ L (liters; occasionally used for displayed or cumulative values)
 - ☐ mL/kg (normalized to predicted body weight)
 - ☐ L/min (if reporting minute ventilation derived from tidal volume \times respiratory rate)
 - c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

8. Respiratory Rate (RR) Values Sampling (breaths/min) (Choose all that apply):

- ☐ Measured
 - a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Ventilator
 - ☐ Capnography
 - ☐ Other, specify:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

b. Body Site:

- ☐ Electrocardiogram/Telemetry
- ☐ Arterial blood pressure
- ☐ Intracranial pressure
- ☐ Cerebral Blood Flow velocity
- ☐ Other, specify:

c. Timing:

- i. Start Date/Time:
- ii. End Date/Time:

☐ Digitized

a. Frequency (Hz):

b. Source of data acquisition:

- ☐ Multiparametric monitor
- ☐ Directly from device
- ☐ Secondly derived from:
 - ☐ Electrocardiogram/Telemetry
 - ☐ Arterial blood pressure
 - ☐ Intracranial pressure
 - ☐ Cerebral Blood Flow velocity
 - ☐ Other, specify:

9. Arterial Blood Pressure (ABP) Waveform Values Sampling (mmHg) (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Multiparametric monitor
- ☐ Other, specify:

b. Body Site:

- ☐ Radial artery
- ☐ Femoral artery
- ☐ Axillary artery
- ☐ Other, specify:

c. Timing:

- a. Start Date/Time:
- b. End Date/Time:

☐ Digitized

a. Frequency (Hz):

b. Source of data acquisition:

- ☐ Multiparametric monitor
- ☐ Directly from device

10. Mean Arterial Blood Pressure (ABP) Values Sampling (mmHg) (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Multiparametric monitor
- ☐ Other, specify:

b. Body Site:

- ☐ Radial artery
- ☐ Femoral artery

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- ☐ Axillary artery
- ☐ Other, specify:

c. Timing:

- i. Start Date/Time:
- ii. End Date/Time:

☐ Digitized

- a. Frequency (Hz):
- b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device
 - ☐ Secondarily derived outside of multiparametric monitor

11. Systolic Arterial Blood Pressure (ABP) Values Sampling (mmHg) (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Multiparametric monitor
- ☐ Other, specify:

b. Body Site:

- ☐ Radial artery
- ☐ Femoral artery
- ☐ Axillary artery
- ☐ Other, specify:

c. Timing:

- i. Start Date/Time:
- ii. End Date/Time:

☐ Digitized

- a. Frequency (Hz):
- b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device
 - ☐ Secondarily derived outside of multiparametric monitor

12. Diastolic Arterial Blood Pressure (ABP) Values Sampling (mmHg) (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Multiparametric monitor
- ☐ Other, specify:

b. Body Site:

- ☐ Radial artery
- ☐ Femoral artery
- ☐ Axillary artery
- ☐ Other, specify:

c. Timing:

- i. Start Date/Time:
- ii. End Date/Time:

☐ Digitized

- a. Frequency (Hz):

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- b. Source of data acquisition:
- ☐ Multiparametric monitor
 - ☐ Directly from device

13. Mean Continuous/Frequent Non-invasive Blood Pressure (NIBP) Values Sampling (mmHg) (Choose all that apply):

- ☐ Measured
- a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Upper arm
 - ☐ Forearm
 - ☐ Wrist
 - ☐ Thigh
 - ☐ Calf
 - ☐ Other, specify:
 - c. Timing:
 - a. Start Date/Time:
 - b. Removed Date/Time:
- ☐ Digitized
- a. Frequency (Hz):
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

14. Systolic Continuous/Frequent Non-invasive Blood Pressure (NIBP) Values Sampling (mmHg) (Choose all that apply):

- ☐ Measured
- a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Upper arm
 - ☐ Forearm
 - ☐ Wrist
 - ☐ Thigh
 - ☐ Calf
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. Removed Date/Time:
- ☐ Digitized
- a. Frequency (Hz):
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

15. Diastolic Continuous/Frequent Non-invasive Blood Pressure (NIBP) Values Sampling (mmHg) (Choose all that apply):

- ☐ Measured
- a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Upper arm
 - ☐ Forearm
 - ☐ Wrist
 - ☐ Thigh
 - ☐ Calf
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. Removed Date/Time:
- ☐ Digitized
- a. Frequency (Hz):
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

16. Cardiac Output (CO) Values Sampling (L/min) (Choose all that apply):

- ☐ Measured
- a. Device Name:
 - ☐ Swan-Ganz
 - ☐ PiCCO
 - ☐ Vigileo
 - ☐ Clearsight
 - ☐ Cheetah
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Pulmonary artery catheter (Swan-Ganz)
 - ☐ Femoral artery (PiCCO)
 - ☐ Radial artery (Vigileo)
 - ☐ Other, specify:
 - c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Digitized
- a. Frequency (Hz):
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

17. Core Temperature Values Sampling (Choose all that apply):

- ☐ Measured
- a. Device Name:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- ☐ Multiparametric monitor
- ☐ Other, specify:

b. Body Site

- ☐ Bladder
- ☐ Skin
- ☐ Esophageal
- ☐ Rectal
- ☐ Other, specify:

c. Timing:

- i. Start Date/Time:
- ii. End Date/Time:

☐ Digitized

- a. Frequency (Hz):
- b. Unit of measurement:
 - ☐ Celsius
 - ☐ Fahrenheit
- c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

18. Targeted Temperature Management Applied Temperature (Choose all that apply):

☐ Collected

- a. Device name:
 - ☐ Arctic Sun
 - ☐ Gentherm Blanketrol III
 - ☐ Other, specify:
- b. Body Site:
 - ☐ Esophageal
 - ☐ Bladder
 - ☐ Rectal
 - ☐ Intravascular catheter
 - ☐ Surface (chest/leg pads, cooling blanket)
 - ☐ Other, specify:
- c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:

☐ Digitized

- a. Frequency (Hz):
- b. Unit of measurement:
 - ☐ Celsius
 - ☐ Fahrenheit
- c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

19. Intracranial Pressure (ICP) Waveform Values from External Ventricular Drain (EVD) Sampling (Choose all that apply):

☐ Collected

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- a. Device Name:
☐ Codman
☐ Integra
☐ Other, specify:
- b. Body Site:
☐ Right frontal
☐ Left frontal
☐ Other, specify:
- c. Timing:
☐ Right Side Insertion:
 i. Start Date/Time:
 ii. End Date/Time:
☐ Left Side Insertion:
 i. Start Date/Time:
 ii. End Date/Time:

- ☐ Digitized
- a. Frequency (Hz):
- b. Unit of measurement:
☐ cmH2O
☐ mmHg
- c. Source of data acquisition:
☐ Multiparametric monitor
☐ Directly from device

20. Intracranial Pressure Values (ICP) Waveform from Parenchymal Catheter Sampling (Choose all that apply):

- ☐ Collected
- a. Device Name:
☐ Raumedic MPR2/NeuroSmart
☐ Integra/Codman/Cerelink
☐ Sophysa
☐ Spiegelberg
☐ Camino/Natus
☐ Raumedic Neurovent (continuous intracranial pressure sensor)
☐ Integra/Natus Flex EVD (continuous intracranial pressure sensor)
☐ Other, specify:
- b. Body Site:
☐ Right frontal
☐ Left frontal
☐ Other, specify:
- c. Timing:
☐ Right Side Insertion:
 i. Start Date/Time:
 ii. End Date/Time:
☐ Left Side Insertion:
 i. Start Date/Time:
 ii. End Date/Time:
- ☐ Digitized
- a. Frequency (Hz):

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- b. Unit of measurement:
 - ☐ cmH2O
 - ☐ mmHg
- c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

21. Brain Temperature Values Sampling (Choose all that apply):

- ☐ Measured
 - a. Device Name:
 - ☐ Raumedic MPR2/NeuroSmart
 - ☐ Sophysa
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Right frontal
 - ☐ Left frontal
 - ☐ Other, specify:
 - c. Timing:
 - ☐ Right Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:
 - ☐ Left Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:

- ☐ Digitized
 - a. Frequency (Hz):
 - b. Unit of measurement:
 - ☐ Celsius
 - ☐ Fahrenheit
 - c. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

22. Cerebral Perfusion Pressure (CPP) Values Sampling (mmHg) (Choose all that apply):

- ☐ Measured
 - a. Source:
 - ☐ Multiparametric monitor
 - ☐ Secondly derived outside of multiparametric monitor
 - b. Body Site:
 - ☐ ICP from Intraparenchymal Probe
 - ☐ Continuous ICP from EVD
 - c. Timing:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Digitized
 - a. Frequency (Hz):
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

☐ Secondly derived outside of multiparametric monitor

23. Brain Tissue Oxygen (PbtO₂) Values Sampling (mmHg) (Choose all that apply):

☐ Measured

a. Device Name:

☐ Integra Licox

☐ Raumedic

☐ Other, specify:

b. Body Site:

☐ Right frontal

☐ Left frontal

☐ Other, specify:

c. Timing:

☐ Right Side Insertion:

i. Start Date/Time:

ii. End Date/Time:

☐ Left Side Insertion:

i. Start Date/Time:

ii. End Date/Time:

☐ Digitized

a. Frequency (Hz):

b. Source of data acquisition:

☐ Multiparametric monitor

☐ Directly from device

24. Near Infrared Spectroscopy (NIRS) Values Sampling (% regional saturation) (Choose all that apply):

☐ Measured

a. Device Name:

☐ Edwards Foresight

☐ Edwards Hemosphere

☐ Medtronic INVOS

☐ Nonin SenSmart

☐ Masimo O3

☐ Other, specify:

b. Body Site:

☐ Right frontal

☐ Left frontal

☐ Bilateral frontal

☐ Parietal

☐ Other, specify:

c. Timing:

☐ Right Side Insertion:

i. Start Date/Time:

ii. End Date/Time:

☐ Left Side Insertion:

i. Start Date/Time:

ii. End Date/Time:

☐ Digitized

a. Frequency (Hz):

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- b. Source of data acquisition:
- ☐ Multiparametric monitor
 - ☐ Directly from device

25. Non-invasive Regional Cerebral Blood Flow (rCBF) Values Sampling (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Delica TCD
- ☐ DWL TCD
- ☐ Rimed TCD
- ☐ Dolphin TCD
- ☐ Spencer TCD
- ☐ Mutligon TCD
- ☐ Lucid TCD
- ☐ NovaGuide TCD
- ☐ Other, specify:

b. Body Site:

- ☐ Right MCA
- ☐ Left MCA
- ☐ Right ICA
- ☐ Left ICA
- ☐ Right PCA
- ☐ Left PCA
- ☐ Other, specify:

c. Timing:

- ☐ Right Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Left Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:

☐ Digitized

a. Frequency (Hz):

b. Units of measurement:

- ☐ mL/100 g/min (if perfusion)
- ☐ cm/s (if velocity trace exported)

c. Source of data acquisition:

- ☐ Multiparametric monitor
- ☐ Directly from device

26. Non-invasive Cerebral Blood Flow Velocity (CBFv) Values Sampling (cm/s) (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Delica TCD
- ☐ DWL TCD
- ☐ Rimed TCD
- ☐ Dolphin TCD
- ☐ Spencer TCD
- ☐ Mutligon TCD

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- ☐ Lucid TCD
- ☐ NovaGuide TCD
- ☐ Other, specify:

b. Body Site:

- ☐ Right MCA
- ☐ Left MCA
- ☐ Right ICA
- ☐ Left ICA
- ☐ Right PCA
- ☐ Left PCA
- ☐ Other, specify:

c. Timing:

- i. Start Date/Time:
- ii. End Date/Time

☐ Digitized

- a. Frequency (Hz):
- b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

27. Invasive Regional Cerebral Blood Flow (rCBF) Values Sampling (Choose all that apply):

☐ Measured

a. Device Name:

- ☐ Hemedex Bowman Perfusion Monitor
- ☐ Other, specify:

b. Body Site:

- ☐
- ☐ Other, specify:

c. Timing:

- ☐ Right Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:
- ☐ Left Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:

☐ Digitized

a. Measurements

- ☐ Tperf (Celsius)
 - a. Frequency (Hz):
- ☐ Δ Tperf (Celsius)
 - a. Frequency (Hz):
- ☐ PerfK
 - a. Frequency (Hz):
- ☐ PerfPPA
 - a. Frequency (Hz):

b. Source of data acquisition:

- ☐ Multiparametric monitor
- ☐ Directly from device

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

28. Cerebral Microdialysis Values Sampling

- ☐ Measured
- a. Device Name:
 - ☐ ISCUSflex
 - ☐ CMA 600 Analyzer
 - ☐ CMA 70/71 catheters
 - ☐ Other, specify
 - b. Body Site:
 - ☐ Right frontal
 - ☐ Left frontal
 - ☐ Pericontusional
 - ☐ Contralateral hemisphere
 - ☐ Other, specify:
 - c. Timing:
 - ☐ Right Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:
 - ☐ Left Side Insertion:
 - i. Start Date/Time:
 - ii. End Date/Time:

- ☐ Digitized
- a. Measurements
 - ☐ Glucose (mmol/L)
 - a. Frequency (Hz):
 - ☐ Glutamate (μ mol/L)
 - b. Frequency (Hz):
 - ☐ Glycerol (μ mol/L)
 - b. Frequency (Hz):
 - ☐ L/P Ratio (ratio)
 - b. Frequency (Hz):
 - ☐ Lactate (mmol/L)
 - b. Frequency (Hz):
 - ☐ Pyruvate (mmol/L)
 - a. Frequency (Hz)
 - b. Source of data acquisition:
 - ☐ Multiparametric monitor
 - ☐ Directly from device

29. Cerebrospinal Fluid Output Technical Aspects:

- ☐ Measured
- a. Device Name:
 - ☐ Multiparametric monitor
 - ☐ Other, specify:
 - b. Body Site:
 - ☐ Ventricular
 - ☐ Lumbar
 - c. Timing:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

i. Start Date/Time:

ii. End Date/Time:

☐ Digitized

c. Frequency (Hz):

d. Units of measurement:

☐ cmH₂O

☐ mmHg

e. Source of data acquisition:

☐ Multiparametric monitor

☐ Directly from device

30. Multiparametric Monitor (Choose all that apply):

☐ Philips

☐ GE

☐ Mindray

☐ Draeger

☐ CNS Monitor

☐ ICM+

☐ Sickbay

☐ BedMaster

☐ Other, specify:

CALCULATED METRICS

(Metadata related to metrics calculated from measured signals)

31. Cardiac Output (CO) Baseline Derivation Values for Cardiac Index Calculation:

☐ Body surface area

☐ Height

☐ Weight

32. Method of calculation of Cerebrovascular Pressure Reactivity Index (PRx) used clinically:

☐ Calculated

a. Method:

☐ Standard calculation

☐ Other, specify:

b. Intracranial Pressure (ICP) component:

☐ Intraparenchymal Probe

☐ Continuous ICP from EVD

c. Device used for calculation:

☐ ICM+

☐ CNS Envision

☐ Raumedic NeuroSmart

☐ Other, specify:

33. Method of calculation of Oxygen Reactivity Index (ORx) used clinically:

☐ Calculated

a. Method:

☐ Standard calculation

☐ Other, specify:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

b. Device used for calculation:

- ☐ ICM+
- ☐ CNS Envision
- ☐ Raumedic NeuroSmart
- ☐ Other, specify:

34. Method of calculation of Cerebral Oximetry Index (COx) used clinically:

- ☐ Calculated
 - a. Method:
 - ☐ Standard calculation
 - ☐ Other, specify:
 - b. Near Infrared Spectroscopy (NIRS) component:
 - ☐ Left only
 - ☐ Right only
 - ☐ Both
 - ☐ Averged left and right
 - c. Device used for calculation:
 - ☐ ICM+
 - ☐ CNS Envision
 - ☐ Other, specify:

35. Method of calculation of Mean Flow Index (Mxa) used clinically:

- a. Method:
 - ☐ Standard calculation
 - ☐ Other, specify:
- b. Device used for calculation:
 - ☐ ICM+
 - ☐ CNS Envision
 - ☐ Other, specify:

36. Method of assessment of Optimal CPP (CPPopt) used clinically:

- a. Method:
 - ☐ Single plot PRx-CPP (per time epoch of interest)
 - ☐ Time trend, specify reference for algorithm:
- b. Device used for calculation:
 - ☐ ICM+
 - ☐ CNS Envision
 - ☐ Raumedic NeuroSmart
 - ☐ Other, specify:

37. Method of assessment of Optimal MAP (MAPopt) used clinically:

- a. Method:
 - ☐ Single plot PRx-CPP (per time epoch of interest)
 - ☐ Time trend, specify reference for algorithm:
- b. Device used for calculation:
 - ☐ ICM+
 - ☐ CNS Envision
 - ☐ Other, specify:
- c. Y-axis trend:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

- ☐ COx
- ☐ Mxa
- ☐ ORx

CLINICAL INDICATIONS AND REASONING

(Indications for monitoring, local protocols of management, contextual information necessary for data interpretation (e.g., relative Body Site of probe placement))

38. End Tidal Carbon Dioxide (EtCO₂) Mode of Ventilation:

- ☐ Nasal Cannula
- ☐ Endotracheal

39. Arterial Blood Pressure (ABP) Leveling:

- ☐ Tragus
- ☐ Phlebostatic axis
- ☐ Other, specify:
- ☐ Unknown

40. Intracranial Pressure Management Approach by External Ventricular Drain (EVD):

- ☐ Open in general with intermittent closure for Intracranial Pressure measurement
- ☐ Closed in general with intermittent drainage or drainage after Intracranial Pressure threshold reached

41. External Ventricular Drain (EVD) Height recorded in these units:

- ☐ cmH₂O
- ☐ mmHg

42. Indication for Monitoring Intracranial Pressure by External Ventricular Drain (EVD) (Choose all that apply):

- ☐ Space-occupying mass
- ☐ Diffuse axonal injury
- ☐ Cerebral edema
- ☐ Hydrocephalus
- ☐ Other, specify:

43. Indication for Monitoring Intracranial Pressure by Parenchymal Catheter (Choose all that apply):

- ☐ Space-occupying mass
- ☐ Diffuse axonal injury
- ☐ Cerebral edema
- ☐ Ventricles too small for external ventricular drain
- ☐ Other, specify:

44. Indication for Placement of Intracranial Pressure by Parenchymal Catheter (Choose all that apply):

- ☐ Pericontusional
- ☐ Nondominant hemisphere
- ☐ Contralateral to craniectomy
- ☐ Other, specify:

45. Indication for Placement of Brain Temperature Probe (Choose all that apply):

- ☐ Fever management
- ☐ Intracranial pressure management

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

☐ Other, specify:

46. Intracranial Pressure Management Local Protocol:

☐ Actively targeted goal: Intracranial Pressure less than (<):

a. Units:

☐ cmH₂O

☐ mmHg

☐ Tiered therapy inclusive of (Choose all that apply):

☐ Cerebral Perfusion Pressure

☐ Brain Tissue Oxygen

47. Goal for Targeted Temperature Management (Choose all that apply):

☐ Fever management

☐ Intracranial pressure management

☐ Goal Temperature:

a. Units:

☐ Celsius

☐ Fahrenheit

☐ mmHg

48. Indication for Assessment of PRx/CPPOpt (Choose all that apply):

☐ Severe Traumatic Brain Injury with disorder of consciousness

☐ High grade Subarachnoid Hemorrhage with disorder of consciousness

☐ Intracerebral hemorrhage with disorder of consciousness

☐ Other, specify:

49. Indication for Monitoring Brain Tissue Oxygen (PbtO₂) (Choose all that apply):

☐ Space-occupying mass

☐ Diffuse axonal injury

☐ Cerebral edema

☐ Risk of cerebral ischemia (e.g. vasospasm)

☐ Other, specify:

50. Indication for Near Infrared Spectroscopy (NIRS) (Choose all that apply):

☐ Acute neurologic event identification

☐ Treatment determination

☐ Autoregulation measurement/optimum blood pressure identification

☐ Oximetry threshold identification

☐ Focal intracranial hemorrhage identification

☐ Other, specify:

51. Indication for placement of regional Cerebral Blood Flow Catheter (Choose all that apply):

☐ Pericontusional

☐ Nondominant hemisphere

☐ Contralateral to craniectomy

☐ Area at risk of ischemia

☐ Grey matter

☐ Other, specify:

Physiology and Big Data

(Study Name/ID pre-filled)

Site Name:
Participant ID:

52. Indication for placement of Cerebral Microdialysis (Choose all that apply):

- ☐ Pericontusional
- ☐ Nondominant hemisphere
- ☐ Contralateral to craniectomy
- ☐ Other, specify:

53. Indication for Assessment of Cerebrospinal Fluid (Choose all that apply):

- ☐ Suspected CNS disorder (e.g., meningitis, encephalitis)
- ☐ CNS disorder follow-up
- ☐ Unexplained seizure
- ☐ Fever of unknown origin
- ☐ Dementia
- ☐ Confusional state
- ☐ Anticoagulant therapy
- ☐ Treatment
- ☐ Contrast material introduction
- ☐ Other, specify:

Recorder Signature:

Date:

Physiology and Big Data CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) is designed to capture continuous/near-continuous physiologic CDEs in participants with mild to severe Traumatic Brain Injury (TBI) in an intensive care unit (ICU).

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types) and should be collected if studies which collect physiology information from TBI participants in the ICU are performed.

The data elements on this CRF Module are part of the NINDS CDE Assessments and Examinations Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

ACQUIRED SIGNALS

For each acquired signal, record the following metadata elements:

- Sampling Status CDEs – Select if the acquired signal was Measured and/or Digitized. Measured indicates the acquired signal sampling occurred on a device. Digitized indicates that the measurement was converted into a digital format for computer analysis.
- Device Name – Select from the permissible values for the monitor/device CDEs. If “Other,” specify the device.
- Body Site / Application Site – Record the site of measurement (e.g., radial vs. femoral artery for ABP, bladder vs. rectal for temperature, left vs. right hemisphere for brain probes, lead for ECG).
- Timing – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Unit of Measurement – Choose the appropriate unit (e.g., mmHg, cm H₂O, %, °C, °F, breaths/min, bpm, mL/100g/min).
- Frequency (Hz) – Enter the digitization or sampling frequency of the signal.
- Source of data acquisition – Indicate whether the signal was acquired via multiparametric monitor, directly from the device, or secondarily derived outside the monitor.
- Derived From (if applicable) – If the variable is not a direct measurement, specify the parent signal(s) (e.g., HR derived from ECG, ABP, or SpO₂; CPP derived from ABP and ICP).
- Other, specify – Provide additional details when permissible values do not capture the measurement method, device, or unit used.

CALCULATED METRICS

- Method – Choose one.
- Device used for calculation – Choose one.
- Other CDEs – Choose one.
- Other, specify – Specify the other method, device, etc., if applicable.

Physiology and Big Data CRF Module Instructions

CLINICAL INDICATION AND REASONING

- CDEs with permissible values – Choose one, unless “(Choose all that apply)” is included in the question text.
- Intracranial Pressure Management Local Protocol / Actively targeted goal: Intracranial Pressure less than (<) – Enter the numerical value that the intracranial pressure actively targeted goal is less than.
- Other, specify – Specify the other Body Site for Core Temperature Measurement or Indication for Assessment of PRx/CPPOpt, if applicable.
- Goal for Targeted Temperature Management / Goal Temperature – Enter the numerical value for goal temperature.

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