



NINDS Common Data Element (CDE) Project

Traumatic Brain Injury Version 3.0

Internal Review / Public Review

Participant Characteristics Subgroup Materials

Subgroup Summary

Instrument

- Alcohol Use Disorders Identification Test – Consumption (AUDIT-C)

Case Report Forms

- Behavioral History
- Demographics
- Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR) Demographics Form
- Significant Medical History
- Socioeconomic Status



NINDS CDE Project Traumatic Brain Injury Version 3.0 Participant Characteristics Subgroup Summary

The NINDS TBI v3.0 Common Data Element (CDE) Participant Characteristics Subgroup reviewed and updated CDEs based on the state of neuroscientific clinical research.

The Participant Characteristics Subgroup focused on variables that describe participant demographics and pre-injury background factors considered important in at least one major area of TBI research, considering TBI across the lifespan and a variety of research study designs and foci (e.g., epidemiologic, clinical, neuroimaging, biomarker research). Participant characteristics are used in TBI research to describe and compare study samples, identify heterogeneity in and moderators of TBI outcomes, and as key patient and care setting background variables to contextualize or interpret findings.

The subgroup reassessed CRFs (Demographics, Socioeconomic Status, Behavioral History, Significant Medical History, Informed Consent) and one instrument (EuroQoL-5 Dimension Questionnaire) that were part of prior NINDS TBI CDE initiatives. The Informed Consent CRF and EuroQoL-5 Dimension Questionnaire were determined not to be within the purview of this subgroup. The Informed Consent CRF was removed from the recommendations, and the EuroQoL-5 Dimension Questionnaire was reassigned to the Outcomes and Endpoints Subgroup for review. The subgroup also evaluated the Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR) Demographics Form developed after the v2.0 CDE was published. Finally, the subgroup expanded their review to include the Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) and Ohio State University TBI Identification Method Short Form (OSU-TBI-ID) instruments.

Overlap addressed with other subgroups includes the Assessments and Examinations Subgroup (recommendation of the OSU-TBI-ID Short Form to collect medical history information) and the Psychosocial Modifiers Subgroup (CDEs and instruments to collect alcohol use information).



Summary of Recommendations

Subdomain	Instrument/CRF Name	Classification	Population
Demographics	Demographics	Disease Core; Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
	Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR) Demographics Form	Disease Core; Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
General Health History	Alcohol Use Disorders Identification Test – Consumption (AUDIT-C)	Supplemental	Adult
	Behavioral History	Supplemental	Adult
	Significant Medical History	Disease Core; Supplemental	Adult; Pediatric
History of Disease/Injury Event	Ohio State University TBI Identification Method Short Form (OSU-TBI-ID)	Pending Classification	Adult; Pediatric
Social Status	Socioeconomic Status	Supplemental – Highly Recommended; Supplemental	Adult; Pediatric

CRFs Reviewed and Not Recommended for v3.0

CRF Name	TBI v2.0 Classification
Informed Consent	Supplemental

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Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) (New for TBI)

Availability	Please visit this website for more information about the instrument: Alcohol Use Disorders Identification Test – Consumption
Classification	Supplemental: Traumatic Brain Injury (TBI)
Short Description of Instrument	The Alcohol Use Disorders Identification Test – Consumption (AUDIT-C) is a brief screening test for heavy drinking and/or active alcohol abuse or dependence. It consists of the first 3 questions from the 10-item Alcohol Use Disorders Identification Test (AUDIT) originally developed by the World Health Organization (Babor et al., 2001) to assess alcohol consumption, drinking behaviors and alcohol-related problems.
Comments/Special Instructions	<p>While the AUDIT has demonstrated validity, its length makes it unlikely to be incorporated into routine general history questionnaires. It was found that the AUDIT-C performed better than the full AUDIT for identifying heavy drinkers (Bush et al., 1998). The AUDIT-C has been validated for identification of alcohol misuse in Veterans Affairs (VA) outpatients (Bradley et al., 2007).</p> <p>Because AUDIT-C is efficient to collect through in-person, electronic, phone, or electronic health records (EHR) (as a common instrument collected in routine care), it could be applicable to any study design. However, it is not applicable to all studies (e.g., pediatric) and would only be important to collect in some TBI studies.</p>
Scoring and Psychometric Properties	<p>Scoring: Each AUDIT-C question is scored 0 to 4 points, and the total score is calculated on a scale of 0 – 12. A score of 0 reflects no alcohol use with an optimal screening threshold of ≥ 4 in men and ≥ 3 in women (Bradley et al., 2003; Bradley et al., 2007; Bush et al., 1998). In general, the higher the score the more likely it is that drinking is affecting an individual's health and safety.</p> <p>Psychometric Properties: In a study of men seen in VA general medicine practices, the AUDIT-C was as sensitive and specific as the full 10-item AUDIT for detection of hazardous drinking or alcohol abuse or dependence (Bush et al., 1998).</p>
Rationale/Justification	<p>Strengths: The AUDIT-C is less cumbersome to administer during a routine physical exam and has been shown to be as sensitive as the 10-item AUDIT in detecting alcohol abuse or dependence (Bush et al., 1998). AUDIT-C is a widely used measure of alcohol consumption that is well-validated to predict heavy drinking and alcohol use disorders in diverse populations.</p> <p>Weaknesses: Fewer studies for women to assess validity. While it appears applicable to all adults and across diverse countries, some authors have noted that standard drink sizes vary by country, which could impact the validity of any efforts to combine data from AUDIT-C across countries. For administration, recommendations are to first define standard drink sizes, based on location (e.g., country, region). The scoring cut-offs may differ the most, but this would happen at the stage of analysis (so it would be possible to adjust based on data collected). Both defining what a standard drink is and the different cut-offs that have been validated for identifying likely alcohol abuse allow for harmonization across groups and countries.</p>

<p>References</p>	<p>Key References:</p> <p>Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med. 1998 Sep 14;158(16):1789-95.</p> <p>Bradley KA, DeBenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR. AUDIT-C as a brief screen for alcohol misuse in primary care. Alcohol Clin Exp Res. 2007 Jul;31(7):1208-17.</p> <p>Additional References:</p> <p>Babor TF, Higgins-Biddle JC, Saunders JB and Monteiro M. AUDIT: The Alcohol Use Disorders Identification Test : guidelines for use in primary health care. Guidelines for Use in Primary Care. Geneva: World Health Organization, 2001 (Second Edition) Retrieved 25Nov2025, from https://www.who.int/publications/i/item/WHO-MSD-MSB-01.6a</p> <p>Bazzo S, Battistella G, Riscica P, Moino G, Dal Pozzo G, Bottarel M, Geromel M, Czerwinsky L. Reliability of a self-report Italian version of the AUDIT-C questionnaire, used to estimate alcohol consumption by pregnant women in an obstetric setting. Riv Psichiatr. 2015 Mar-Apr;50(2):89-94.</p> <p>Bradley KA, Bush KR, Epler AJ, Dobie DJ, Davis TM, Sporleder JL, Maynard C, Burman ML, Kivlahan DR. Two brief alcohol-screening tests From the Alcohol Use Disorders Identification Test (AUDIT): validation in a female Veterans Affairs patient population. Arch Intern Med. 2003 Apr 14;163(7):821-9.</p> <p>Bradley KA, Bush KR, McDonell MB, Malone T, Fihn SD; Ambulatory Care Quality Improvement Project. Screening for problem drinking : Comparison of CAGE and AUDIT. J Gen Intern Med. 1998 Jun;13(6):379-88.</p> <p>Frank D, DeBenedetti AF, Volk RJ, Williams EC, Kivlahan DR, Bradley KA. Effectiveness of the AUDIT-C as a screening test for alcohol misuse in three race/ethnic groups. J Gen Intern Med. 2008 Jun;23(6):781-7.</p> <p>García Carretero MÁ, Novalbos Ruiz JP, Martínez Delgado JM, O'Ferrall González C. Validation of the Alcohol Use Disorders Identification Test in university students: AUDIT and AUDIT-C. Adicciones. 2016 Mar 2;28(4):194-204. English, Spanish</p> <p>Källmén H, Berman AH, Jayaram-Lindström N, Hammarberg A, Elgán TH. Psychometric Properties of the AUDIT, AUDIT-C, CRAFFT and ASSIST-Y among Swedish Adolescents. Eur Addict Res. 2019;25(2):68-77.</p> <p>Kolšek M, Poplas Susič T, Kersnik J. Slovenian adaptation of the original AUDIT-C questionnaire. Subst Use Misuse. 2013 Jun;48(8):581-9.</p>
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MD+CALC. AUDIT-C for Alcohol Use. Retrieved 25Nov2025, from <https://www.mdcalc.com/calc/2021/audit-c-alcohol-use>

TBI-Specific References:

Eyer MM, Renier CM, Woehrle TA, Vogel LE, Conway PG, McCarty CA. Alcohol Use at the Time of Traumatic Brain Injury: Screening and Brief Intervention in a Community Hospital. J Trauma Nurs. 2017 Mar/Apr;24(2):116-124.

Li A, Walter A, Lee MD, Diaz-Arrastia R, Sandsmark D. Comparison of Emergency Room and Self-reported Alcohol Use in Individuals with Traumatic Brain Injury (P6-7.007). Neurology 2025 08 Apr;104 7(Suppl 1). Abstract.

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Behavioral History

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

~~During the past 30 days, how many days per month did you have at least one drink of any alcoholic beverage such as beer, wine, a malt beverage or liquor?~~

~~During the past 30 days, on the days when you drank, about how many drinks did you drink on the average?~~

~~Considering all types of alcoholic beverages, how many times during the past 30 days did you have X [X = 5 for men, X = 4 for women] or more drinks on an occasion?~~

1. Indicates alcohol use prior to the last 12 months:
☐ Yes ☐ No ☐ Unknown
2. Alcohol use duration in years:
3. Current tobacco/nicotine use?
☐ Yes ☐ No ☐ Unknown
4. Past tobacco/nicotine use?
☐ Yes ☐ No ☐ Unknown
5. Tobacco/nicotine use duration in years:
6. Type(s) of tobacco/nicotine products used (Choose all that apply):
☐ Filtered cigarettes
☐ Non-filtered cigarettes
☐ Light/low tar cigarettes
☐ Cigars
☐ Pipes
☐ Smokeless tobacco (chewing tobacco, snuff, snus)
☐ Electronic cigarettes/vaping devices (e-cigarettes, vape pens, pods)
☐ Heated tobacco products
☐ Nicotine pouches
☐ Other, specify:
7. Indicates cannabis/marijuana use in the past year:
☐ Yes ☐ No ☐ Unknown
8. Indicates cannabis/marijuana use prior to the past 12 months:
☐ Yes ☐ No ☐ Unknown
9. Duration in years of cannabis/marijuana use:
10. If YES, specify cannabis/marijuana type(s) used (Choose all that apply):
☐ Cannabis/marijuana (flower, plant material)
☐ Cannabis concentrates (hash, wax, shatter, dabs)
☐ Cannabis edibles
☐ Synthetic cannabinoids (K2, Spice, synthetic marijuana)
☐ Marijuana, hash, THC, or grass
11. Indicates illicit drug use in the past year:
☐ Yes ☐ No ☐ Unknown
12. Indicates illicit drug use prior to the past 12 months:
☐ Yes ☐ No ☐ Unknown
13. Duration in years of illicit drug use:
14. If YES, specify illicit drug type(s) used (Choose all that apply):

Central Nervous System Stimulants

- ☐ Cocaine (powder)
- ☐ Crack cocaine
- ☐ Amphetamines (including methamphetamine, crystal meth)
- ☐ MDMA/Ecstasy/Molly
- ☐ Synthetic cathinones (bath salts, flakka)
- ☐ Prescription stimulants used non-medically (Adderall, Ritalin, Concerta)

Behavioral History

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Opioids

- ☐ Heroin
- ☐ Prescription opioid painkillers used non-medically (oxycodone, hydrocodone, morphine, fentanyl, tramadol, codeine)
- ☐ Synthetic opioids (illicit fentanyl, nitazenes)
- ☐ Opium

Hallucinogens and Dissociatives

- ☐ ~~(e.g. ecstasy, LSD, mescaline, psilocybin, PCP, angel dust, or peyote)~~
- ☐ Psilocybin mushrooms
- ☐ DMT
- ☐ Mescaline/peyote
- ☐ PCP (angel dust)
- ☐ Ketamine (when used non-medically)
- ☐ Salvia divinorum
- ☐ Other novel psychoactive substances/designer drugs

Central Nervous System Depressants

- ☐ Marijuana, hash, THC, or grass
- ☐ Prescription sedatives/tranquilizers used non-medically (benzodiazepines: Xanax, Valium, Ativan; barbiturates)
- ☐ GHB (gamma-hydroxybutyric acid)
- ☐ Rohypnol

Inhalants

- ☐ ~~Inhalants or Volatile solvents (e.g. amyl nitrate, nitrous oxide, glue, toluene, or gasoline, paint thinners)~~
- ☐ Aerosols (spray paints, deodorants, hair sprays)
- ☐ Nitrites (poppers, rush, locker room odorizers)

Other Substances

- ☐ Kratom
- ☐ Dextromethorphan (DXM, when used to get high)
- ☐ Anabolic steroids (when used non-medically)
- ☐ Other novel psychoactive substances (NPS)
- ☐ ~~Narcotics: (heroin, opium morphine, methadone)~~
- ☐ ~~Painkillers (e.g. Codeine, Darvon, Percadon, Dilaudid, or Demerol)~~
- ☐ ~~Sedatives (e.g. sleeping pills, barbiturates, Seconal, Quaaludes, or Chloral Hydrate)~~
- ☐ ~~Stimulants (e.g. Preludin, Benzedrine, Methadrine, uppers, or speed)~~
- ☐ ~~Stimulants: amphetamine, Benzedrine~~
- ☐ ~~Stimulants: cocaine/crack~~
- ☐ ~~Tranquilizers or anti-anxiety drugs (e.g. Valium, Librium, muscle relaxants, or Xanax)~~
- ☐ Other, specify: ~~(e.g., Methadone, Elavil, steroids, Thorazine, or Haldol)~~

Recorder Signature:

Date:

Behavioral History CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) collects information on behavioral history related to substance use, which may be relevant to traumatic brain injury (TBI) research and other clinical studies.

To assess the participant's history of alcohol, use the [Alcohol Use Disorders Identification Test – Consumption \(AUDIT-C\)](#), a brief screening test for heavy drinking and/or active alcohol abuse or dependence.

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 and should only be collected if the research team considers them appropriate for their study design and type(s).

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.

Alcohol Use Assessment

- AUDIT-C implementation: The AUDIT-C is a validated 3-question screening tool that identifies persons with hazardous drinking or active alcohol use disorders. Scores of 3 or higher in women and 4 or higher in men are considered positive screens.
- Indicates alcohol use prior to the last 12 months – Choose one. Document when the behavioral history was collected to determine whether this information was obtained prior to study enrollment or later. Response is obtained by report of the participant or proxy as soon as possible after visit/admission.
- Alcohol use duration – Response is obtained by report of the participant or proxy as soon as possible after visit/admission. Document when the behavioral history was collected. National Institute on Drug Abuse (NIDA) drug categories and terminology: [Drugs A to Z | National Institute on Drug Abuse \(NIDA\)](#)

Tobacco/Nicotine Use Assessment

- Current tobacco/nicotine use? – Choose one. Response is obtained from participant, family member, friend, or medical record. Add date stamp for when assessed. Recommend collection at least on date of TBI.
- Past tobacco/nicotine use? – Choose one. Response is obtained by report of the participant or proxy as soon as possible after visit/admission. Document when the behavioral history was collected.
- Tobacco/nicotine use duration in years – Response is obtained by report of the participant or proxy. Document when the behavioral history was collected.
- Type(s) of tobacco/nicotine products used – Updated to include modern nicotine delivery systems including e-cigarettes, vaping devices, heated tobacco products, and nicotine pouches. Choose all that apply.

Cannabis and Marijuana Use Assessment

- Indicates cannabis/marijuana use in the past year – Choose one. Response is obtained from participant, family member, friend, or medical record. Add date stamp for when assessed. Recommend collection at least on date of TBI.
- Indicates cannabis/marijuana use prior to the past 12 months – Choose one. Response is obtained by report of the participant or proxy as soon as possible after visit/admission. Document when the behavioral history was collected.
- Duration in years of cannabis/marijuana use – Response is obtained by report of the participant or proxy. Document when the behavioral history was collected.
- Specify cannabis/marijuana type(s) used – Choose all that apply.

Behavioral History CRF Module Instructions

Illicit Drug and Substance Use Assessment

- Drug or substance use indicators – Choose one. Response is obtained by report of the participant or proxy as soon as possible after visit/admission. Document when the behavioral history was collected.
- Important – Do not record medications that are prescribed for medical purposes (these should be entered in 'Prior and Concomitant Medications CRF'). Collect information on substances and medications taken for reasons other than prescription, or taken more frequently or at higher doses than prescribed.
- Confidentiality – Assure participant that information on substance use will be treated as strictly confidential.
- Timing – Substance use directly before injury may have contributed to the incident causing injury. In general, substance use may indicate increased risk-taking behavior.
- Updated categories – The substance categories have been updated to reflect current drug trends and include:
 - Modern synthetic drugs and novel psychoactive substances
 - Cannabis concentrates and edibles
 - Prescription drug misuse categories
 - Current street drug terminology
 - Emerging substances like kratom and synthetic opioids

Data Collection Best Practices

- Recommend collection as soon as possible after visit/admission
- Document whether information was obtained prior to study enrollment or later
- Use non-judgmental language when collecting sensitive information
- Ensure privacy and confidentiality during data collection
- Consider cultural and linguistic factors that may affect reporting

- ~~• Alcohol use last month days drank count – The suggested range is 0–30.~~
- ~~• Alcohol use last month drinking day average drinks count – Response is obtained from report by participant/subject or proxy. Recommend collection as soon as possible after visit/admission.~~
- ~~• Alcohol use last month consumed more than four or five drinks days count – The suggested range is 0–30.~~
- ~~• Alcohol prior use indicator – Choose one. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Substance abuse directly before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~
- ~~• Alcohol use duration – Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Substance abuse directly before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~
- ~~• Tobacco current use indicator – Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record. Add date stamp for when assessed. Recommend collection at least on date of TBI.~~
- ~~• Tobacco prior use indicator – Choose one. Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Substance abuse directly before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~
- ~~• Tobacco use duration – Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Substance abuse directly~~

Behavioral History CRF Module Instructions

~~before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~

- ~~• Tobacco product used type—Choose all that apply. Response is obtained from report by participant/subject or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission.~~
- ~~• Tobacco product used other text—Choose all that apply. Response is obtained from report by participant/subject or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission.~~
- ~~• Drug or substance current illicit use indicator—Choose one. Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Do not record medications that are prescribed for medical purposes (these should be entered in the element 'medical history'.) Collect information on substances and medications taken for reasons other than prescription, or taken more frequently or at higher doses than prescribed. Assure participant/subject that information on such use will be treated as strictly confidential. Recommend collection as soon as possible after visit/admission. Substance abuse directly before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~
- ~~• Drug or substance prior illicit use indicator—Choose one. Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Do not record medications that are prescribed for medical purposes (these should be entered in the element 'medical history'.) Collect information on substances and medications taken for reasons other than prescription, or taken more frequently or at higher doses than prescribed. Assure participant/subject that information on such use will be treated as strictly confidential. Recommend collection as soon as possible after visit/admission. Substance abuse directly before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~
- ~~• Drug or substance illicit use duration—Response is obtained by report of the participant/subject or proxy as soon as possible after visit/admission. Document when the behavioral history was collected so as to determine whether this information was obtained prior to study enrollment or later. Do not record medications that are prescribed for medical purposes (these should be entered in the element 'medical history'.) Collect information on substances and medications taken for reasons other than prescription, or taken more frequently or at higher doses than prescribed. Assure participant/subject that information on such use will be treated as strictly confidential. Recommend collection as soon as possible after visit/admission. Substance abuse directly before injury may have contributed to the incident causing injury. In general, substance abuse may indicate increased risk taking behavior.~~
- ~~• Subscribed drug or substance illicitly used category—Choose all that apply. Response is obtained from report by participant/subject or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission.~~
- ~~• Subscribed drug or substance illicitly used category other text—Choose all that apply. Response is obtained from report by participant/subject or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission.~~

REFERENCES

Corrigan JD, Bogner J, Holloman C. Lifetime history of traumatic brain injury among persons with substance use disorders. *Brain Inj.* 2012;26(2):139-50.

Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. *Arch Intern Med.* 1998;158(16):1789-95.

Please refer to the PhenX Toolkit Substance Use, Use Disorders, and Recovery Collections:

Behavioral History CRF Module Instructions

<https://www.phenxtoolkit.org/collections/view/2>, the Behavioral Risk Factor Surveillance System (BRFSS) instrument for capturing alcohol consumption <https://www.cdc.gov/brfss/>, and the National Institute on Drug Abuse (NIDA) drug categories and terminology: <https://nida.nih.gov/>

Demographics

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. *Birth date:
2. Birth time:
3. **Age (years):
~~If less than 3 years of age (in months):~~

~~*Gender (Choose one):~~

- ☐ ~~Male~~
- ☐ ~~Female~~
- ☐ ~~Unknown~~
- ☐ ~~Unspecified~~
- ☐ ~~Not reported~~

4. *Sex at birth (Choose one):

- ☐ Male
- ☐ Female

5. ~~*Genotypic sex (Choose one):~~

- ☐ XX
- ☐ XY
- ☐ XXX
- ☐ XXY
- ☐ XYY
- ☐ Unspecified
- ☐ Unknown
- ☐ Other, specify

6. *Ethnicity (Choose one):

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown
- ☐ Not Reported
- ☐ ~~Other, specify:~~

7. *Race Category (Choose all that apply):

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown
- ☐ Not reported

Demographics

[Study Name/ID pre-filled]

Site Name:
Participant ID:

8. *Race (Choose all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Alaskan Native | <input type="checkbox"/> Western Asian |
| <input type="checkbox"/> Black African | <input type="checkbox"/> White African |
| <input type="checkbox"/> Black African American | <input type="checkbox"/> White Australian |
| <input type="checkbox"/> Black Afro Caribbean | <input type="checkbox"/> White European |
| <input type="checkbox"/> Far Eastern Asian | <input type="checkbox"/> White Middle Eastern |
| <input type="checkbox"/> Hawaiian | <input type="checkbox"/> White North American |
| <input type="checkbox"/> Inuit | <input type="checkbox"/> White South American |
| <input type="checkbox"/> North American Indian | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Pacific Islander | <input type="checkbox"/> Other |
| <input type="checkbox"/> South/Central American Indian | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> South Asian | |

9. **Primary language (ISO 639-2 code):

- ☐ English (eng)
- ☐ Spanish (spa)
- ☐ ~~Sign Languages (sgn)~~
- ☐ Chinese languages (chi)
- ☐ Tagalog (tgl)
- ☐ Vietnamese (vie)
- ☐ Arabic (ara)
- ☐ French (fre)
- ☐ Korean (kor)
- ☐ Portuguese (por)
- ☐ Russian (rus)
- ☐ ~~German (ger)~~
- ☐ Other, specify ISO 639-2 code:

10. Language spoken fluently (ISO 639-2 code):

- ☐ English (eng)
- ☐ Spanish (spa)
- ☐ ~~Sign Languages (sgn)~~
- ☐ Chinese languages (chi)
- ☐ Tagalog (tgl)
- ☐ Vietnamese (vie)
- ☐ Arabic (ara)
- ☐ French (fre)
- ☐ Korean (kor)
- ☐ Portuguese (por)
- ☐ Russian (rus)
- ☐ ~~French/Creole (cpf)~~
- ☐ ~~German (ger)~~
- ☐ ~~Italian (ita)~~
- ☐ ~~Polish (pol)~~
- ☐ Other, specify ISO 639-2 code:

11. Language written fluently (ISO 639-2 code):

- ☐ English (eng)
- ☐ Spanish (spa)
- ☐ Chinese languages (chi)
- ☐ Tagalog (tgl)
- ☐ Vietnamese (vie)

Demographics

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ Arabic (ara)
- ☐ French (fre)
- ☐ Korean (kor)
- ☐ Portuguese (por)
- ☐ Russian (rus)
- ☐ ~~German (ger)~~
- ☐ Other, specify ISO 639-2 code:

12. Birth country name (ISO 3166 1 alpha 2 code):

13. Hand preference type: ☐ Left hand ☐ Right hand ☐ Both hands ☐ Unknown

Additional Pediatric-specific Elements

These elements are recommended for pediatric studies.

~~Date and time of birth:~~

~~Date (m m / d d / y y y y):~~

~~Time: ☐ AM ☐ PM ☐ 24 hour clock~~

14. Maternal ethnicity ("X" ONLY one with which the mother MOST CLOSELY identifies):

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown
- ☐ Not Reported

15. Maternal race ("X" those with which the mother identifies):

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown
- ☐ Not reported

16. Paternal ethnicity ("X" ONLY one with which the father MOST CLOSELY identifies):

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown
- ☐ Not Reported

17. Paternal race ("X" those with which the father identifies):

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown
- ☐ Not reported

Recorder Signature:

Date:

Demographics CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

Important note: Some of the data elements are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies) or Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below.

*Element is classified as Disease Core

**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).

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

Please see the Data Dictionary for element classifications.

~~Important note: Four of the data elements included on this CRF are classified as Core (i.e., strongly recommended for all TBI studies to collect) or Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by the asterisk below.~~

~~*Element is classified as Core:~~

~~Birth date~~

~~Gender type~~

~~Sex genotype type~~

~~Sex participant or subject genotype other text~~

~~Ethnicity USA category~~

~~Race USA category~~

~~Race expanded category~~

~~**Element is classified as Basic for Concussion/Mild TBI studies:~~

~~Age value~~

~~Language primary ISO code~~

~~Language primary other text~~

~~Language primary text~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

~~The remaining elements are Supplemental and should be collected only if the research team considers them appropriate for their study.~~

As stated in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects ~~participants/subjects~~ in Clinical Research: The Office of Management and Budget (OMB) [Directive No. 15](#) defines the minimum standard of basic racial and ethnic categories, which are used below. NIH has chosen to continue the use of these definitions because they allow comparisons across many national databases, especially national health databases. Therefore, the racial and ethnic categories described below should be used as basic guidance, cognizant of the distinction based on cultural heritage. (<https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline>)

Demographics CRF Module Instructions

Responses to categories are obtained from self-report when possible or obtained from parent/legal guardian interview.

SPECIFIC INSTRUCTIONS

Please see the [Data Dictionary](#) for definitions for each of the data elements included in this CRF Module.

- Birth date – 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.
- Birth time – This element may be included if relevant to the study. Use a 24-hour clock.
- Age – Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded. Record age at the level of precision appropriate to the study. For most adult studies, truncating age to the current integer value is adequate. For children (age < 18 years), it is recommended to include decimals. Note that age > 89 may constitute a patient identifier. Under U.S. federal regulations, age > 89 can be recorded as a single value (e.g., 90+) when de-identification is desired. For children younger than one year born at less than 36 weeks gestation, it is recommended to also collect gestational age.
- ~~Less three years age value – For children younger than one year born at less than 36 weeks gestation, it is recommended to also collect gestational age. Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded.~~
- ~~Gender type – Choose one. Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically.~~
 - ~~Unspecified is defined as Undifferentiated/Indeterminant/Intersex~~
- Sex at birth – Choose one.
- Genotypic sex – Choose one.
- Ethnicity – Choose only one with which the participant/~~subject~~ most closely identifies.
- Race Category – Choose all that apply.
- Race – Choose all that apply. Response is obtained by participant/~~subject~~ or caretaker report. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of ~~subjects~~ participants enrolled on an annual basis using the racial categories listed.
- Primary language ISO code – Choose one. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
- Language spoken fluently ISO code – Choose all that apply. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
- Language written fluently ISO code – Choose all that apply. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
- Birth country ~~name~~ – Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes.
- Hand preference type – Choose one.
- Maternal ethnicity – Choose only one that the participant's/~~subject's~~ mother most closely identifies ~~with~~.
- Maternal race – Choose all those racial categories that the participant's/~~subject's~~ mother most closely identifies with.
- Paternal ethnicity – Choose only one that the participant's/~~subject's~~ father most closely identifies ~~with~~.
- Paternal race - Choose all those racial categories that the participant's/~~subject's~~ father most closely identifies with.

Demographics CRF Module Instructions

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ISO 3166-1 alpha-2 codes (<https://www.iso.org/iso-3166-country-codes.html>)

ISO 639-2 language codes (https://www.loc.gov/standards/iso639-2/php/code_list.php)

ISO 8601 - <https://www.iso.org/standards.html>

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FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Name:

Visit Date:

Main Group Administration Questions

Study Name:

1. GUID:

2. Participant ID Number:

3. **Age in Years:

4. Visit Date:

5. Site Name:

6. Days since Baseline:

~~Case Control Indicator~~

☐ ~~Case~~

☐ ~~Control~~

☐ ~~Unknown~~

Form Administration

7. What time frame do the questions in this form refer to?

Select one. If other is selected, please write in response:

- ☐ After injury
- ☐ At time of assessment
- ☐ Before injury
- ☐ Last 2 weeks
- ☐ Last 6 months
- ☐ Last 24 hours
- ☐ Last month
- ☐ Last week
- ☐ Last year
- ☐ Prior to death
- ☐ Since last interview
- ☐ Time of injury
- ☐ Other, specify:

8. Who filled out this form?

Select one. If other is selected, please write in response:

- ☐ Brother
- ☐ Chart/Medical Record
- ☐ Daughter
- ☐ Father

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ Friend
- ☐ Mother
- ☐ Participant
- ☐ Physician
- ☐ Sister
- ☐ Son
- ☐ Spouse
- ☐ Other, specify:

Demographics Questions

9. *What is the participant's date of birth?

Write in response.

~~*What is the participant's gender?~~

~~Select one:~~

- ☐ ~~Female~~
- ☐ ~~Male~~
- ☐ ~~Not reported~~
- ☐ ~~Unknown~~
- ☐ ~~Unspecified~~

10. *Sex at birth (Select one):

- ☐ Male
- ☐ Female

11. ~~*What is the participant's sex or genotype?~~ Genotypic sex:

Select one. If other is selected, please write in response:

- ☐ XX
- ☐ XY
- ☐ XXX
- ☐ XXY
- ☐ XYY
- ☐ Unknown
- ☐ Unspecified
- ☐ Other, specify:

12. What is the participant's handedness preference, or dominant hand?

Select one:

- ☐ Both ~~hands~~
- ☐ Left ~~hand~~
- ☐ Right ~~hand~~
- ☐ Unknown

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

13. *What is the participant's racial background (as defined by OMB)?

Select all that apply.

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☒ Other
- ☐ Not Reported
- ☐ Unknown

14. *What is the participant's racial background (expanded categories)?

Select all that apply.

- ☐ Alaskan Native
- ☐ Black African
- ☐ Black African American
- ☐ Black Afro Caribbean
- ☐ Far Eastern Asian
- ☐ Hawaiian
- ☐ Inuit
- ☐ North American Indian
- ☐ Pacific Islander
- ☐ South/Central American Indian
- ☐ South Asian
- ☐ Western Asian
- ☐ White African
- ☐ White Australian
- ☐ White European
- ☐ White Middle Eastern
- ☐ White North American
- ☐ White South American
- ☐ Not Reported
- ☐ Other
- ☒ Unknown

15. *What is the participant's ethnic background?

Select one: If other is selected, please write in response:

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Not reported
- ☐ Unknown
- ☒ ~~Other, specify:~~

16. What is the participant's birth country (use ISO code)?

For full list of codes, see BirthCntryISOCODE variable in the data dictionary and provide information in the

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Other category

Select one: If other is selected, please write in response:

- ☐ Australia (AU)
- ☐ Canada (CA)
- ☐ Mexico (MX)
- ☐ United Kingdom (GB)
- ☐ USA (US)
- ☐ Other, specify:

17. What is the participant's birth country name?

Write in response.

18. What is the participant's current country of residence?

For full list of codes, see CntryResdncelISOCode variable in the data dictionary and provide information in the

Other category

Select one: If other is selected, please write in response:

- ☐ Australia (AU)
- ☐ Canada (CA)
- ☐ Mexico (MX)
- ☐ United Kingdom (GB)
- ☐ USA (US)
- ☐ Other, specify:

19. What is the participant's current country of residence name?

Write in response.

20. ******What is the participant's primary language (use ISO code)?

Select one: If other is selected, please write in response:

- ☐ English (eng)
- ☐ Spanish (spa)
- ☐ ~~sgn (Sign Language)~~
- ☐ Chinese languages (chi)
- ☐ Tagalog (tgl)
- ☐ Vietnamese (vie)
- ☐ Arabic (ara)
- ☐ French (fre)
- ☐ Korean (kor)
- ☐ Portuguese (por)
- ☐ Russian (rus)
- ☐ ~~ger (German)~~
- ☐ Other, specify **ISO 639-2 code:**

21. What are the ISO codes for each language the participant can speak fluently? The ISO codes represent the international codes for different countries.

Write in response.

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

22. Please list each language the participant can speak fluently:

Write in response.

23. What are the ISO codes for each language the participant can write fluently?

Write in response.

24. Please list each language the participant can write fluently:

Write in response.

25. ******What is the participant's marital status?

Select one: If other is selected, please write in response:

- ☐ Never married
- ☐ Married
- ☐ ~~Domestic partnership~~ Living with partner
- ☐ Divorced
- ☐ Separated
- ☐ Widowed
- ☐ Unknown
- ☐ Other, specify:

26. If an adult: Who is the primary person living with the participant?

Select one: If other is selected, please write in response:

- ☐ Alone
- ☐ Shared accommodation (independent)
- ☐ With spouse/partner
- ☐ With children
- ☐ With parents/siblings
- ☐ Homeless
- ☐ Military barracks
- ☐ In supervised care
- ☐ Unable to obtain information
- ☐ Other, specify:
- ☐ ~~Child/children~~
- ☐ ~~Group living situation, boarding house~~
- ☐ ~~Other (including correctional facility inmates)~~
- ☐ ~~Other patients (in hospital/nursing home)~~
- ☐ ~~Other residents~~
- ☐ ~~Parents~~
- ☐ ~~Personal care attendant~~
- ☐ ~~Roommates/friends~~
- ☐ ~~Siblings~~
- ☐ ~~Significant other partner~~
- ☐ ~~Spouse (including common law partner)~~

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

27. If a juvenile: What is the participant's living situation?

Select one: If other is selected, please write in response:

- ☐ Adoptive parents
- ☐ Foster care
- ☐ Other family members
- ☐ Parents
- ☐ Unable to obtain information
- ☐ Other, specify:

28. What was the participant's living situation ~~prior~~**before** to injury?

Select one: If other is selected, please write in response:

- ☐ Homeless/Lives in shelter
- ☐ Lives alone
- ☐ Lives in group home/assisted living
- ☐ Lives with friend(s) or roommate(s) or cohabiting
- ☐ Lives with spouse and/or other family member(s)
- ☐ Data Missing/Refused/Unknown
- ☐ Other, specify:

29. What is the count of other people with whom the participant currently lives, cohabits, or stays?

Write in response.

30. What is the number of dependent children living in the participant's household?

Write in response.

31. What is the total number of dependent children the participant has?

Write in response.

32. How would you describe the participant's current location of residence?

Select one:

- ☐ A big city (population greater than or equal to 250,000 including suburbs/outskirts)
- ☐ A small town/small city (population 500 - 10,000)
- ☐ Rural area (population less than 500)
- ☐ Unknown

33. What type of residence does the participant currently live in?

Select one: If other is selected, please write in response:

- ☐ Home
- ☐ Hospital
- ☐ Nursing home
- ☐ Rehabilitation center
- ☐ Unknown
- ☐ N/A – participant died
- ☐ Other, specify:

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

34. Approximately, what is the current annual income of the participant's household?

Select one:

- ☐ ~~Under \$15,000~~
- ☐ Less than \$10,000
- ☐ \$10,000-\$24,999
- ☐ ~~\$15,000 to \$24,999~~
- ☐ \$25,000 - \$34,999
- ☐ \$35,000 - \$49,999
- ☐ \$50,000 - \$74,999
- ☐ \$75,000 - \$99,999
- ☐ ~~\$100,000 and over~~
- ☐ \$100,000-\$149,999
- ☐ \$150,000-\$199,999
- ☐ \$200,000 or more
- ☐ Unknown
- ☐ Refused to answer

35. What is the value, in U.S. dollars, of annual pre-tax, pre-deduction total income, of the participant's household?

Write in response. Please select one of the questions regarding income, you do not need to use both.

36. What is the number of people supported by the above income?

Write in response.

37. How many wage earners live in the participant's household?

Write in response.

38. Does the participant's income meet the participant's household's basic needs?

Select one:

- ☐ Very poorly
- ☐ Rather poorly
- ☐ Adequately (neither well nor poorly)
- ☐ Rather well
- ☐ Very well
- ☐ Unknown
- ☐ Refused to answer

39. ******What best describes the highest level the participant completed in school?

Select one:

- ☐ Never attended/Kindergarten only
- ☐ 1st Grade
- ☐ 2nd Grade
- ☐ 3rd Grade
- ☐ 4th Grade
- ☐ 5th Grade

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ 6th Grade
- ☐ 7th Grade
- ☐ 8th Grade
- ☐ 9th Grade
- ☐ 10th Grade
- ☐ 11th Grade
- ☐ 12th Grade, no diploma
- ☐ GED or equivalent
- ☐ High school graduate
- ☐ Some college, no degree
- ☐ Associate degree: occupational/technical/vocational program
- ☐ Associate degree: academic program
- ☐ Bachelor's degree (e.g., BA, AB, BS, BBA)
- ☐ Master's degree (e.g., MA, MS, MEng, MEd, MBA)
- ☐ Professional school degree (e.g., MD, DDS, DVM, JD)
- ☐ Doctoral degree (e.g., PhD, EdD)
- ☐ Unknown

40. What type of education did the participant receive?

~~Select one:~~ **Select all that apply:** *If other is selected, please write in response:*

- ☐ Home school
- ☐ Private
- ☐ Public
- ☐ Other, specify:

41. How many years of education does the participant have?

Write in response.

42. What is the highest level of education the participant received pre-injury?

Select one:

- ☐ None/basic primary = 0 - 4 years
- ☐ Primary/Intermediate Primary = 5 - 8 years
- ☐ Secondary = 12 years
- ☐ Tertiary = 13 - 15 years (e.g., Teachers, Technicians)
- ☐ University = 16 - 17 years
- ☐ Post Graduate = 18 - 19 years (e.g., Masters, Doctoral)
- ☐ Unknown

43. ***What is the participant's current attendance in school?**

Select one:

- ☐ Going to school
- ☐ On vacation from school (between grades)
- ☐ Neither
- ☐ Unknown

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

44. What is the type of education the participant receives with details of being with or without assistance?

Select one: If other is selected, please write in response:

- ☐ Full-time regular education without aide
- ☐ Full-time regular education with one to one aide
- ☐ Regular education with pull-out for certain areas
- ☐ Special education w/minimal inclusion (e.g., lunch)
- ☐ Full-time regular education with no inclusion
- ☐ Home-schooled
- ☐ Special (MR/DD) school
- ☐ Not in school
- ☐ Other, specify:

45. ******What is the participant's current primary occupational status?

Select one: If other is selected, please write in response:

- ☐ Paid work (employed/self-employed, including military)
 - ☐ Special employment (sheltered workshop, supportive employment, job coach)
 - ☐ Temporary/odd jobs/less than minimum wage jobs
 - ☐ Working less than 20 hours/week, at least minimum wage
 - ☐ Working 20-34 hours/week, at least minimum wage
 - ☐ Working full time (35 hours or more/week, at least minimum wage)
 - ☐ Working, details unknown
- ☐ Only temporarily laid off, sick leave, or parental leave
- ☐ Retired (self-defined)
- ☐ Disabled, permanently or temporarily (self-defined)
- ☐ Student (including on the job training)
- ☐ Homemaker/unpaid caregiver
- ☐ ~~Unemployed (none of the above)~~
- ☐ Unemployed, looking for employment (none of the above)
- ☐ Unemployed, not looking for employment (none of the above)
- ☐ Unpaid work (volunteer, internship)
- ☐ Unknown
- ☐ Not applicable (child)
- ☐ Other, specify:

~~47. What is the status of the participant's current employment?~~

~~*Select one: If other is selected, please write in response:*~~

- ☐ ~~Not in paid workforce (including child, retired, student, homemaker, disabled pre-injury)~~
- ☐ ~~Sick leave or maternity leave~~
- ☐ ~~Special employment (sheltered workshop, supportive employment, job coach)~~
- ☐ ~~Temporary/odd jobs/less than minimum wage jobs~~
- ☐ ~~Working 20-34 hours/week, at least minimum wage~~
- ☐ ~~Working less than 20 hours/week, at least minimum wage~~
- ☐ ~~Working full time (35 hrs or more/week, at least minimum wage)~~
- ☐ ~~Unemployed~~
- ☐ ~~Unknown~~

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

☐ ~~Other, specify:~~

46. What was the participant's pre-injury job classification?

Select one: If other is selected, please write in response:

- ☐ Officials and managers
- ☐ Professionals
- ☐ Technicians
- ☐ Sales workers
- ☐ Administrative support workers
- ☐ Craft workers
- ☐ Operatives
- ☐ Labors and helpers
- ☐ Service workers
- ☐ Not applicable
- ☐ Unknown
- ☐ Other, specify:

- ☐ ~~Agricultural or fishery worker~~
- ☐ ~~Armed forces~~
- ☐ ~~Clerk~~
- ☐ ~~Craft or trades worker~~
- ☐ ~~Elementary worker~~
- ☐ ~~Legislator, or senior official, or manager~~
- ☐ ~~Plant/machine operator or assembler~~
- ☐ ~~Professional~~
- ☐ ~~Service or sales worker~~
- ☐ ~~Technician or Associate~~

47. What is the participant's current job classification?

Select one: If other is selected, please write in response:

- ☐ Officials and managers
- ☐ Professionals
- ☐ Technicians
- ☐ Sales workers
- ☐ Administrative support workers
- ☐ Craft workers
- ☐ Operatives
- ☐ Labors and helpers
- ☐ Service workers
- ☐ Not applicable
- ☐ Unknown
- ☐ Other, specify:

- ☐ ~~Agricultural or fishery worker~~
- ☐ ~~Armed forces~~
- ☐ ~~Clerk~~
- ☐ ~~Craft or trades worker~~

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

- ☐ ~~Elementary worker~~
- ☐ ~~Legislator, or senior official, or manager~~
- ☐ ~~Plant/machine operator or assembler~~
- ☐ ~~Professional~~
- ☐ ~~Service or sales worker~~
- ☐ ~~Technician or Associate~~

48. What is the participant's reason for being unemployed?

Write in response.

FITBIR Demographics Parent, Guardian, or Caregiver Info

49. What is the relationship between the person who acts as the primary caregiver for the participant and the participant?

Select all that apply. If other is selected, please write in response:

- ☐ Adoptive father
- ☐ Adoptive mother
- ☐ Adoptive parents
- ☐ Biological father
- ☐ Biological father - not a primary caregiver
- ☐ Biological mother
- ☐ Biological mother - not a primary caregiver
- ☐ Biological parents
- ☐ Child
- ☐ Grandfather
- ☐ Grandmother
- ☐ Home aide
- ☐ Legal guardian
- ☐ Long-term care staff/nursing facility staff
- ☐ Parent
- ☐ Relative
- ☐ Self
- ☐ Sibling
- ☐ Spouse or partner
- ☐ Stepfather
- ☐ Stepmother
- ☐ Stepparent
- ☐ Unknown
- ☐ Other, specify:

50. What are the living statuses of the ~~subject's~~ participant's parents?

Select all that apply:

- ☐ Father alive
- ☐ Father deceased
- ☐ Father unknown
- ☐ Mother alive

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

- ☐ Mother deceased
☐ Mother unknown

~~*What is the parent, guardian, or caregiver's gender?~~

~~Select one:~~

- ☐ ~~Female~~
☐ ~~Male~~
☐ ~~Not reported~~
☐ ~~Unknown~~
☐ ~~Unspecified~~

51. What is the parent, guardian, or caregiver's sex at birth?

Select one:

- ☐ Male
☐ Female

52. *What is the parent, guardian, or caregiver's race, based on the OBM race standards?

Select all that apply:

- ☐ American Indian or Alaska Native
☐ Asian
☐ Black or African-American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Other
☐ Not Reported
☐ Unknown

53. * What is the parent, guardian, or caregiver's race, using expanded race categories?

Select all that apply:

- ☐ Alaskan Native
☐ Black African
☐ Black African American
☐ Black Afro Caribbean
☐ Far Eastern Asian
☐ Hawaiian
☐ Inuit
☐ North American Indian
☐ Pacific Islander
☐ South/Central American Indian
☐ South Asian
☐ Western Asian
☐ White African
☐ White Australian
☐ White European
☐ White Middle Eastern

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

- ☐ White North American
- ☐ White South American
- ☐ Other
- ☐ Not Reported
- ☐ Unknown

54. *What is the parent, guardian, or caregiver's ethnicity?

Select one. If other is selected, please write in response:

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Not reported
- ☐ Unknown
- ☐ Other, specify:

55. What is the parent, guardian, or caregiver's birth country ISO code?

For full list of codes, see BirthCntryISOCode variable in the data dictionary

Select one. If other is selected, please write in response:

- ☐ Australia (AU)
- ☐ Canada (CA)
- ☐ Mexico (MX)
- ☐ United Kingdom (GB)
- ☐ USA (US)
- ☐ Other, specify:

56. What is the parent, guardian, or caregiver's birth country name?

Write in response

57. What is the parent, guardian, or caregiver's marital status?

Select one. If other is selected, please write in response:

- ☐ Never married
- ☐ Married
- ☐ ~~Domestic partnership~~ Living with partner
- ☐ Divorced
- ☐ Separated
- ☐ Widowed
- ☐ Unknown
- ☐ Other, specify:

58. What is the number of dependent children living in the parent, guardian, or caregiver's household?

Write in response

59. What is the total number of dependent children the parent, guardian, or caregiver has?

Include both living in the household and living elsewhere.

Write in response

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

60. How would you describe the parent, guardian, or caregiver's current location of residence?

Select one:

- ☐ A big city (population greater than or equal to 250,000 including suburbs/outskirts)
- ☐ A small town/small city (population 500 - 10,000)
- ☐ Rural area (population less than 500)
- ☐ Unknown

61. What type of residence does the parent, guardian, or caregiver currently live in?

Select one. If other is selected, please write in response:

- ☐ Home
- ☐ Hospital
- ☐ Nursing home
- ☐ Rehabilitation center
- ☐ Unknown
- ☐ N/A – participant patient died
- ☐ Other, specify:

62. Approximately, what is the current annual income of the parent, guardian, or caregiver's household?

Select one:

- ☐ ~~Under \$15,000~~
- ☐ ~~Less than \$10,000~~
- ☐ ~~\$10,000-\$24,999~~
- ☐ ~~\$15,000 to \$24,999~~
- ☐ \$25,000 - \$34,999
- ☐ \$35,000 - \$49,999
- ☐ \$50,000 - \$74,999
- ☐ \$75,000 - \$99,999
- ☐ ~~\$100,000 and over~~
- ☐ \$100,000-\$149,999
- ☐ \$150,000-\$199,999
- ☐ \$200,000 or more
- ☐ Unknown
- ☐ Refused

63. What is the value, in U.S. dollars, of annual pre-tax, pre-deduction total income, of the parent, guardian, or caregiver's household?

Free-form version of the above question. Researchers' please select one version of asking this question.

64. What is the number of people supported by the above income?

Write in response

65. **What is the parent, guardian, or caregiver's highest grade or level of school completed?

Select one

- ☐ Never attended/Kindergarten only
- ☐ 1st Grade

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ 2nd Grade
- ☐ 3rd Grade
- ☐ 4th Grade
- ☐ 5th Grade
- ☐ 6th Grade
- ☐ 7th Grade
- ☐ 8th Grade
- ☐ 9th Grade
- ☐ 10th Grade
- ☐ 11th Grade
- ☐ 12th Grade, no diploma
- ☐ GED or equivalent
- ☐ High school graduate
- ☐ Some college, no degree
- ☐ Associate degree: occupational/technical/vocational program
- ☐ Associate degree: academic program
- ☐ Bachelor's degree (e.g., BA, AB, BS, BBA)
- ☐ Master's degree (e.g., MA, MS, MEng, MEd, MBA)
- ☐ Professional school degree (e.g., MD, DDS, DVM, JD)
- ☐ Doctoral degree (e.g., PhD, EdD)
- ☐ Unknown

66. How many years of education does the parent, guardian, or caregiver have?

Write in response

67. What is the **primary caregiver's** (parent, guardian, or **other** caregiver's) current primary occupational status?

Select one. If other is selected, please write in response:

- ☐ Paid work (employed/self-employed, including military)
 - ☐ Special employment (sheltered workshop, supportive employment, job coach)
 - ☐ Temporary/odd jobs/less than minimum wage jobs
 - ☐ Working less than 20 hours/week, at least minimum wage
 - ☐ Working 20-34 hours/week, at least minimum wage
 - ☐ Working full time (35 hours or more/week, at least minimum wage)
 - ☐ Working, details unknown
- ☐ Only temporarily laid off, sick leave, or parental leave
- ☐ Retired (self-defined)
- ☐ Disabled, permanently or temporarily (self-defined)
- ☐ Student (including on the job training)
- ☐ Homemaker/unpaid caregiver
- ☐ ~~Unemployed (none of the above)~~
- ☐ Unemployed, looking for employment (none of the above)
- ☐ Unemployed, not looking for employment (none of the above)
- ☐ Unpaid work (volunteer, internship)
- ☐ Unknown

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

- ☐ Not applicable
☐ Other, specify:

~~70. What is the status of the parent, guardian, or caregiver's current employment?~~

~~Select one. If other is selected, please write in response:~~

- ☐ ~~Not in paid workforce (including child, retired, student, homemaker, disabled pre-injury)~~
☐ ~~Sick leave or maternity leave~~
☐ ~~Special employment (sheltered workshop, supportive employment, job coach)~~
☐ ~~Temporary/odd jobs/less than minimum wage jobs~~
☐ ~~Working 20-34 hours/week, at least minimum wage~~
☐ ~~Working less than 20 hours/week, at least minimum wage~~
☐ ~~Working full time (35 hrs or more/week, at least minimum wage)~~
☐ ~~Unemployed~~
☐ ~~Unknown~~
☐ ~~Other, specify:~~

68. What is the parent, guardian, or caregiver's job classification?

Select one:

- ☐ Officials and managers
☐ Professionals
☐ Technicians
☐ Sales workers
☐ Administrative support workers
☐ Craft workers
☐ Operatives
☐ Labors and helpers
☐ Service workers
☐ Not applicable
☐ Unknown
☐ None
☐ Administration
☐ Social Worker

~~What is the parent, guardian, or caregiver's reason for being unemployed?~~

~~Write in response~~

FITBIR Demographics Military Info

If the participant was not in the military, please disregard this section

69. Is the participant active military?

Select one:

- ☐ Yes
☐ No
☐ Unknown

70. What is the military occupational status of the participant?

Select one. If other is selected, please write in response:

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ Combat
- ☐ Non-Combat
- ☐ Other, specify:

71. Which branch of service in the U.S. Military is the participant involved?

Select one. If other is selected, please write in response:

- ☐ Air Force
- ☐ Air Force Reserves
- ☐ Air National Guard
- ☐ Army
- ☐ Army National Guard
- ☐ Army Reserves
- ☐ Coast Guard
- ☐ Coast Guard Reserves
- ☐ Marine Corps
- ☐ Marine Corps Reserves
- ☐ Navy
- ☐ Navy Reserves
- ☐ Space Force
- ☐ Other, specify:

72. What is the participant's military rank?

Select one. If other is selected, please write in response:

- ☐ Company grade officer
- ☐ Field grade officer or above
- ☐ Non-commissioned officer (e.g., sergeant/corporal)
- ☐ Warrant officer
- ☐ Other, specify:

73. Where was the participant deployed?

Select one. If other is selected, please write in response:

- ☐ Afghanistan
- ☐ Africa
- ☐ Germany
- ☐ Iraq
- ☐ Not provided
- ☐ None
- ☐ Other, specify:

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

FITBIR Demographics Sports Info

If the participant did not participate in any sports in his or her lifetime, please disregard this section

74. Was the participant's traumatic brain injury sports related?

Select one:

- ☐ Yes
☐ No
☐ Unknown

75. Answer the following questions if the participant attended elementary school:

Did the participant participate in sports in elementary school?

Select one:

- ☐ Yes
☐ No

76. What was the primary sport the participant played in elementary school?

Write in response

77. How many years did the participant play the primary sport in elementary school?

Select one:

- ☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6

78. Which other sports did the participant play in elementary school?

Write in response

79. What are the total combined years the participant played the other sports in elementary school?

Write in response

80. Answer the following questions if the participant attended junior high school:

Did the participant participate in sports in junior high school?

Select one:

- ☐ Yes
☐ No

81. What was the primary sport the participant played in junior high school?

Write in response

82. How many years did the participant play the primary sport in junior high school?

Select one:

- ☐ 1

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

83. Which other sports did the participant play in junior high school?

Write in response

84. How many total combined years did the participant play other sports in junior high school?

Write in response

85. Answer the following questions if the participant attended high school:

Did the participant participate in sports in high school?

Select one:

- ☐ Yes
- ☐ No

86. What was the primary sport the participant played in high school?

Write in response

87. How many years did the participant play the primary sport in high school?

Select one:

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

88. Which other sports did the participant play in high school?

Write in response

89. How many total combined years did the participant play other sports in high school?

Write in response

Answer the following questions if the participant attended college:

90. Did the participant participate in sports in college?

Select one:

- ☐ Yes
- ☐ No
- ☐ Unknown

91. What was the primary sport the participant played in college?

Select one. If other is selected, please write in response:

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ Baseball
- ☐ Basketball
- ☐ Bowling
- ☐ Boxing
- ☐ Cross Country/Track
- ☐ Diving
- ☐ Equestrian
- ☐ Fencing
- ☐ Field Event
- ☐ Field Hockey
- ☐ Figure Skating
- ☐ Football
- ☐ Golf
- ☐ Gymnastics
- ☐ Ice Hockey
- ☐ Ice Skating
- ☐ Lacrosse
- ☐ Rifle
- ☐ Rowing
- ☐ Skiing
- ☐ Soccer
- ☐ Softball
- ☐ Swimming
- ☐ Tennis
- ☐ Volleyball
- ☐ Water Polo
- ☐ Wrestling
- ☐ Other, specify:

92. How many years did the participant play the primary sport in college?

Write in response

93. Which other sports did the participant play in college?

Write in response

94. How many total combined years did the participant play other sports in college?

Write in response

95. Did the participant participate in recreational sports?

Select one:

- ☐ Yes
- ☐ No

96. What is the primary recreational sport played by the participant?

Write in response

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:
Participant ID:

97. How many years did the participant play the primary recreational sport?

Write in response

98. Which other recreational sports did the participant play?

Write in response

99. How many total combined years did the participant play other recreational sports?

Write in response

100. Did the participant participate in professional sports?

Select one:

- ☐ Yes
☐ No
☐ Unknown

101. What was the primary professional sport the participant played?

Select one. If other is selected, please write in response:

- ☐ Baseball
☐ Basketball
☐ Bowling
☐ Boxing
☐ Cross Country/Track
☐ Diving
☐ Equestrian
☐ Fencing
☐ Field Event
☐ Field Hockey
☐ Figure Skating
☐ Football
☐ Golf
☐ Gymnastics
☐ Ice Hockey
☐ Ice Skating
☐ Lacrosse
☐ Rifle
☐ Rowing
☐ Skiing
☐ Soccer
☐ Softball
☐ Swimming
☐ Tennis
☐ Volleyball
☐ Water Polo
☐ Wrestling

FITBIR Demographics Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

☐ Other, specify:

102. What is the total number of years the participant played the primary professional sports?

Write in response

103. Which other professional sports did the participant play?

Write in response

104. What is the total number of years the participant played other professional sports?

Write in response

Recorder Signature:

Date:

FITBIR Demographics Form CRF Module Instructions

GENERAL INSTRUCTIONS

Federal Interagency Traumatic Brain Injury Research (FITBIR) Demographics Form contains data elements that are collected to describe the demographics of the study population relevant to TBI research.

Important note: Some of the data elements are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies) or Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below. Martial/partner status and current occupational status are recommended for adult studies. Caregiver level of education is recommended for pediatric studies.

*Element is classified as Disease Core

**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).

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

Please see the Data Dictionary for element classifications.

~~Important note: Some of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect), as indicated by the asterisk below.~~

~~*Element is classified as Core:~~

~~Birth date~~

~~Gender type~~

~~Sex genotype type~~

~~Race USA category~~

~~Race expanded category~~

~~Ethnicity USA category~~

~~Education school participation status~~

~~Parent gender type~~

~~Parent Race USA Category~~

~~Parent race expanded category~~

~~Parent Ethnicity USA category~~

~~The remaining data elements are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

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

- Participant ID Number – The participant or subject identifiers or IDs should be assigned by the study.
- Age in Years – Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit

FITBIR Demographics Form CRF Module Instructions

discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded. Record age at the level of precision appropriate to the study. For most adult studies, truncating age to the current integer value is adequate. For children (age < 18 years), it is recommended to include decimals. Note that age > 89 may constitute a patient identifier. Under U.S. federal regulations, age > 89 can be recorded as a single value (e.g., 90+) when de-identification is desired. For children younger than one year born at less than 36 weeks gestation, it is recommended to also collect gestational age. ~~The subject's age is typically recorded to the nearest full year completed, e.g., 11 years and 6 months should be recorded as 11 years. For subject's which are under 1 year old, use decimal points and use the following convention: record 1 month as 0.083 (1/12), 2 months as 0.166 (2/12), 3 months as 0.25 (3/12), 4 months as 0.333 (4/12), 5 months as 0.416 (5/12), 6 months as 0.5 (6/12), 7 months as 0.583 (7/12), 8 months as 0.666 (8/12), 9 months as 0.75 (9/12), 10 months as 0.833 (10/12), 11 months as 0.916 (11/12) and 12 months as 1 year.~~

- Visit Date – 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.
- Site Name – Enter the name of the study site.
- Days since Baseline – Enter the number of days passed since the baseline visit.
- ~~Case Control Indicator – Indicate whether subject is (was) in the case or control arm of the study.~~
- What time frame do the questions in this form refer to? – This question should be the first required question in the repeatable group which contains time frame, context dependent questions.
- Who filled out this form? – Choose all that apply.
- What is the participant's date of birth? – 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. Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded. Data Sharing Instructions: When date/time data are prepared for aggregation or sharing they should be converted to the format specified by ISO 8601, YYYY-MM-DDT:hh:mm:ss.
- ~~Gender type – Choose one. Response is obtained by report of the participant or caretaker. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 (http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)~~
- Sex at birth – Choose one.
- Genotypic sex – Choose only one.
- What is the participant's handedness preference, or dominant hand? – The purpose of this element is to determine dominant hemisphere; therefore, for those who were originally left-handed but forced to write right-handed, record left-handed. Choose one - the hand which the participant/subject uses predominantly, not necessarily the hand the participant writes with exclusively. Choose the hand which the participant/subject uses predominantly, not necessarily the hand the participant writes with exclusively. Unknown should be used in the scenario for infants or other (rare) instances when handedness cannot be known or is not yet developed.
- What is the participant's racial background (as defined by OMB)? Choose all that apply. Response is obtained by participant/subject or caretaker report. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. (<https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline>) The Office of Management and

FITBIR Demographics Form CRF Module Instructions

Budget (OMB) [Directive No. 15](#) defines the minimum standard of basic racial and ethnic categories.

- What is the participant's racial background (expanded categories)?– Choose all that apply. Response is obtained by report of the participant or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.
- What is the participant's ethnic background? –Choose one. Response is obtained by report of the participant or caretaker. If more detailed characterizations of ethnicity are collected to enhance data quality and consistency, it is recommended that they be "collapsible" up to the two categories for reportable ethnicity, as needed for reporting to FDA under its guidance. Other regulatory bodies may expect the reporting of ethnicity values which more appropriately reflect the population of their areas (e.g., Japanese ancestry for MHLW reporting to Japan). These may be collected as an extension to the suggested code list. The NIH Policy and Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget [Directive No. 15](#) defines the minimum standard of basic racial and ethnic categories. (<https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline>) Collection of Race and Ethnicity Data in Clinical Trials (FDA, October 2016 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials>).
- What is the participant's birth country (use ISO code)? – Choose only one country where the participant was born. ~~which the subject/participant currently lives.~~ If the country code is not included on the form then code the data later using ISO 3166-1 alpha-2 codes. If ISO code does not exist, use Country of residence birth name CDE to write the country name. If the country code is not included on the form, then code the data later using ISO 3166-1 alpha-2 codes. (<https://www.iso.org/iso-3166-country-codes.html>)
- What is the participant's birth country name? – Text for participant's birth country. It may be easier to record the full name of the country and code the data later in Birth country ISO code using the ISO 3166-1 alpha-2 codes.
- What is the participant's current country of residence? – Choose only one country in which the participant currently lives. If the country code is not included on the form then code the data later using ISO 3166-1 alpha-2 codes. If ISO code does not exist, use Country of residence name CDE to write the country name. If the country code is not included on the form, then code the data later using ISO 3166-1 alpha-2 codes. ISO 3166-1 alpha-2 codes. (<https://www.iso.org/iso-3166-country-codes.html>)
- What is the participant's current country of residence name? – This CDE should be used in combination with Country of residence ISO code CDE when there is no ISO code available for the country name. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes.
- What is the participant's primary language (use ISO code)? – Choose one. It may be easier to record the full name of the language using Language primary text and code the data later using the ISO 639-2 alpha-3 codes. Data Sharing Instructions: The language data should be coded using the ISO 639-2 codes prior to aggregation or sharing.
- What are the ISO codes for each language the participant can speak fluently? – Choose all that apply. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes. The language data should be coded using the ISO 639-2 codes prior to aggregation or sharing.
- Please list each language the participant can speak fluently – Text for all languages participant speaks fluently. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes. The language data should be coded using the ISO 639-2 codes prior to aggregation or sharing.
- What are the ISO codes for each language the participant can write fluently? – Enter all that apply.
- Please list each language the participant can write fluently – Text for all languages participant writes fluently. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
- What is the participant's marital status? – Choose one. ~~STROKE: Johnson NJ, Backlund E, Sorlie PD,~~

FITBIR Demographics Form CRF Module Instructions

~~Loveless CA. Marital status and mortality: the national longitudinal mortality study. Ann Epidemiol. 2000;10:224-238. NCI CDE Browser Public ID = 2188083~~

- If an adult: Who is the primary person living with the participant? – Choose one.
- If a juvenile: What is the participant's living situation? – Living situation of juvenile
- What was the participant's living situation prior to injury? – Living situation of the participant before injury.
- What is the count of other people with whom the participant currently lives, cohabits, or stays? – Include everyone who is living or staying here for more than 2 months. ~~Include participant if they are living here for more than 2 months.~~ Include anyone else staying here who does not have another place to stay even if they are here for 2 months or less. Do not include anyone who is living somewhere else for more than 2 months, such as college student living away or someone in the Armed Forces on deployment. Answer should be recorded as a 2-digit number (i.e., one should be recorded as 01, ten should be recorded as 10). Participants should NOT be included.
- What is the number of dependent children living in the participant's household? – Number of dependent children for a participant.
- What is the number of dependent children living in the participant's household? – Write in response.
- What is the total number of dependent children the participant has? – Write in response.
- How would you describe the participant's current location of residence? – Choose one.
- What type of residence does the participant currently live in? – Choose one. If other is selected, please write in response.
- Approximately, what is the current annual income of the participant's household? – Choose one. This includes pre-tax cash income earned by people, money wages and salaries, self-employment income, property income (dividends, interest and rents), money transfer payments from a variety of government and private welfare and social insurance schemes (such as social security, unemployment and workers compensation, and public assistance), private and government retirement income, interpersonal transfers (such as alimony and child support) and other periodic income. This excludes certain lump sum payments and capital gains. Add date stamp for when assessed. Recommend collection at least on date of TBI and perhaps after all initial medical treatment.
- What is the number of people supported by the above income? – Add date stamp for when assessed. Recommend collection at least on date of TBI and perhaps after all initial medical treatment. Count of all people, including the participant, who are supported by the household gross annual income reported.
- How many wage earners live in the participant's household? – Refer to Household and Income.
- Does the participant's income meet the participant's household's basic needs? – Choose one.
- What best describes the highest level the participant completed in school? – Choose the highest level attained by the participant.
- What type of education did the participant receive? – Choose all that apply.
- How many years of education does the participant have? – ~~Choose the highest level attained by the participant~~ For years completed, starting with 1st grade, code the number of years attained (0-30 years), normed to someone moving full time at the usual pace, i.e., a year that was repeated counts as only 1 year and the usual single-year full-time load completed over several years counts as 1 year. Certificate and technical programs do NOT count no matter how specialized. ~~The number of years of typical completion of the relevant program is counted.~~ To consistently award years based on level of education, number of years aligns with highest level of schooling completed as follows: high school diploma (12 years), associate degree (14 years), bachelor's degree (16 years), master's degree (18 years), one doctoral degree (19-20 years for a 3-4-year doctoral degree, respectively). Post-secondary education that was insufficient to earn a degree will generally fall in between these benchmarks. If the participant obtained their education outside the United States, ask about their educational system to estimate the correct coding - Internship, Residency, and Fellowship years are experiential training and do not count. Recommend collection at least on date of TBI.
- What is the highest level of education the participant received pre-injury? – Choose one.
- What is the type of education the participant receives with details of being with or without assistance? –

FITBIR Demographics Form CRF Module Instructions

~~This element can be collected to describe the participant prior to the stroke event and to assess the participant at subsequent time points after the stroke event. Choose one. If other is selected, please write in response.~~

- What is the participant's current primary occupational status? – Choose one. May also be useful to record occupational status at time of injury.
- ~~Employment expanded status—Prior TBI studies utilized the Employment Status data element for data capture. Choose one.~~
- What was the participant's pre-injury job classification?— For detailed definitions go to: <http://www.who.int/healthinfo/survey/whsshortversionguide.pdf> Explanations of the categories can be found on the U.S. Equal Employment Opportunity Commission website: <https://www.eeoc.gov/federal-sector/reports/appendix-i-glossary-definitions>
- ~~Job classification category~~ What is the participant's current job classification? – For detailed definitions go to: <http://www.who.int/healthinfo/survey/whsshortversionguide.pdf> Explanations of the categories can be found on the U.S. Equal Employment Opportunity Commission website: <https://www.eeoc.gov/federal-sector/reports/appendix-i-glossary-definitions>
- What is the participant's reason for being unemployed? – Specify the reason for unemployment.
- What is the relationship between the person who acts as the primary caregiver for the participant and the participant? – Type of relationship between the person who acts as the primary caregiver for the participant and the participant.
- What are the living statuses of the participant's parents?— Specifies whether the participant's parents are still living. Answer for both parents.
- ~~Parent gender type—Self-reported gender of the participant's parent. Gender is the socially constructed identity of sex. Choose one. The participant or parent, guardian, or caretaker obtain response.~~
- What is the parent, guardian, or caregiver's sex at birth? – Choose one. The participant or parent, guardian, or caretaker obtain response.
- What is the parent, guardian, or caregiver's race, based on the OBM race standards?— The participant's parent self-declared racial origination, independent of ethnic origination, using OMB approved categories. Choose all that apply. Response is obtained by report of the participant or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.
- What is the parent, guardian, or caregiver's race, using expanded race categories? – Category of race(s) or region(s) the parent, guardian, or caregiver most closely identifies with. Choose all that apply. Response is obtained by report of the participant or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subject's enrolled on an annual basis using the racial categories listed.
- What is the parent, guardian, or caregiver's ethnicity? – Choose one. Response is obtained by report of the participant or caretaker. If more detailed characterizations of ethnicity are collected to enhance data quality and consistency, it is recommended that they be "collapsible" up to the two categories for reportable ethnicity, as needed for reporting to FDA under its guidance. Other regulatory bodies may expect the reporting of ethnicity values which more appropriately reflect the population of their areas (e.g., Japanese ancestry for MHLW reporting to Japan). These may be collected as an extension to the suggested code list. The NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget [Directive No. 15](https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline) define the minimum standard of basic racial and ethnic categories. (<https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline>) Collection of Race and Ethnicity Data in Clinical Trials (FDA, October 2016 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials>).

FITBIR Demographics Form CRF Module Instructions

- What is the parent, guardian, or caregiver's birth country ISO code? – Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes. Code (ISO 3166-1 alpha-2 code) for country where the participant's parent, guardian, or caregiver was born.
- What is the parent, guardian, or caregiver's birth country name? – Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes. Code (ISO 3166-1 alpha-2 code) for country where the participant was born
- What is the parent, guardian, or caregiver's marital status? – ~~STROKE: Johnson NJ, Backlund E, Sorlie PD, Loveless CA. Marital status and mortality: the national longitudinal mortality study. Ann Epidemiol. 2000;10:224-238. Status of participant's current domestic relationship, whether marital or partnered.~~
- What is the number of dependent children living in the parent, guardian, or caregiver's household? – Refer to Household and Income.
- What is the total number of dependent children the parent, guardian, or caregiver has? – Include both living in the household and living elsewhere.
- How would you describe the parent, guardian, or caregiver's current location of residence? – Choose one.
- What type of residence does the parent, guardian, or caregiver's currently live in? – Choose one. Add date and time stamp for when assessed.
- Approximately, what is the current annual income of the parent, guardian, or caregiver's household? – Choose one.
- What is the value, in U.S. dollars, of annual pre-tax, pre-deduction total income, of the parent, guardian, or caregiver's household? – Free-form version of the above question. Researchers' please select one version of asking this question.
- What is the number of people supported by the above income? – Write in response.
- What is the parent, guardian, or caregiver's highest grade or level of school completed? – Choose the highest level attained by the participant's primary caregiver. This element is recommended for Pediatric ~~stroke~~TBI studies. Choose highest level attained.
- How many years of education does the parent, guardian, or caregiver have? – Record years of education following the same rules as detailed above for participant years of education. To apply to international setting, this data element was made to supplement. ~~For years completed, code the number of years attained (0-30 years), normed to someone moving full time at the usual pace, i.e. a year that was repeated counts as only 1 year and the usual single year full time load completed over several years counts as 1 year. Certificate and technical programs do NOT count no matter how specialized. The number of years of typical completion of the relevant program is counted. If the participant's primary caregiver obtained their education outside the United States, ask about their educational system to estimate the correct coding—Internship, Residency, and Fellowship years are experiential training and do not count. Recommend collection at least on date of TBI.~~
- What is the primary caregiver's (parent, guardian, or other caregiver's) current primary occupational status? – Choose one. If other is selected, please write in response.
- What is the parent, guardian, or caregiver's job classification? - Explanations of the categories can be found on the U.S. Equal Employment Opportunity Commission website: <https://www.eeoc.gov/federal-sector/reports/appendix-i-glossary-definitions>
- ~~Parent unemployed reason~~
- the participant active military? – Whether participant currently has active military status.
- What is the military occupational status of the participant? – Military occupational status of participant.
- Which branch of service in the U.S. Military is the participant involved? – Choose one. Response is obtained by report of the participant or relatives.
- What is the participant's military rank? – Choose one. Response is obtained by report of the participant or relatives. NATO rank specifications could be used instead, but military personnel are typically unfamiliar with these ranks (i.e., they do not know their own NATO rank specifications). Ranks generally reflect level of responsibility and type of activities engaged in while in theatre - information that may correlate with risk/severity/type of injury. If Active, Active reserves Inactive or Civilian Military

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Contractor, specify. Military service status.

- Where was the participant deployed? – Region or country the military participant was deployed.
- Was the participant's traumatic brain injury sports related? – The indicator related to having an injury of head or neck in sports.
- Did the participant participate in sports in elementary school? – The indicator related to whether participant played in sport(s) in elementary school.
- What was the primary sport the participant played in elementary school? – The free-text field to specify the primary sport the participant played in elementary school.
- How many years did the participant play the primary sport in elementary school? – The number of years participant played sport(s) in elementary school.
- Which other sports did the participant play in elementary school? – The free-text field to specify which other sports the participant played in elementary school.
- What are the total combined years the participant played the other sports in elementary school? – Total combined number of years the participant played other sport(s) in elementary school.
- Did the participant participate in sports in junior high school? – The indicator related to whether participant played sports in junior high school.
- What was the primary sport the participant played in junior high school? – The indicator related to which sports participant played in junior high school.
- How many years did the participant play the primary sport in junior high school? – The number of years participant played sport(s) in junior high school.
- Which other sports did the participant play in junior high school? – The free-text field to specify which other sports participant played in junior high school.
- How many total combined years did the participant play other sports in junior high school? – Total combined number of years participant played sport(s) junior high school.
- How many total combined years did the participant play other sports in college? – Use in combination with Other sport(s) the participant played in college.
- Did the participant participate in sports in high school? – Choose one.
- What was the primary sport the participant played in high school? – Write in response.
- How many years did the participant play the primary sport in high school? – Choose one.
- Which other sports did the participant play in high school? – Write in response.
- How many total combined years did the participant play other sports in high school? – Write in response.
- Did the participant participate in sports in college? – Choose one.
- What was the primary sport the participant played in college? – Choose one. If other is selected, please write in response.
- How many years did the participant play the primary sport in college? – Write in response.
- Which other sports did the participant play in college? – Write in response.
- How many total combined years did the participant play other sports in college? – Write in response.
- Did the participant participate in recreational sports? – Choose one.
- What is the primary recreational sport played by the participant? – Write in response.
- How many years did the participant play the primary recreational sport? – Write in response.
- Which other recreational sports did the participant play? – Write in response.
- How many total combined years did the participant play other recreational sports? – Write in response.
- Did the participant participate in professional sports? – Choose one.
- What was the primary professional sport the participant played? – Choose one. If other is selected, please write in response.
- What is the total number of years the participant played the primary professional sports? – Use in combination with Primary professional sport played by the participant.
- Which other professional sports did the participant play? – Write in response.
- What is the total number of years the participant played other professional sports? – Use in

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combination with Other professional sports played by the participant.

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Significant Medical History

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. ~~**~~Number of **lifetime** concussions prior to the current injury:

Additional Supplemental Elements:

~~These elements may be included if relevant to the study.~~

2. Source of medical information (Choose all that apply):

- ☐ Medical record
- ☐ Patient
- ☐ Healthcare provider
- ☐ Informant (Choose one):
 - ☐ Parent
 - ☐ Child
 - ☐ Partner/Spouse
 - ☐ Other, specify:
- ☐ Other, specify:
- ☐ Unknown

3. ~~Medical history for body system indicator~~

Does the participant have a history of any medical problems/conditions in the following body systems?

- ☐ Yes
- ☐ No
- ☐ Unknown

4. Body system category (Choose one for each medical condition reported):

- ☐ Allergic/Immunologic
- ☐ Cardiovascular
- ☐ Constitutional symptoms (e.g., fever, weight loss)
- ☐ Dermatological
- ☐ Ears, Nose, Mouth, Throat
- ☐ Endocrine
- ☐ Eyes
- ☐ Gastrointestinal
- ☐ Gastrointestinal/Abdominal
- ☐ Genitourinary
- ☐ Gynecologic/Urologic/Renal
- ☐ Hematologic/Lymphatic
- ☐ Hepatobiliary
- ☐ Integumentary (skin and/or breast)
- ☐ Musculoskeletal
- ☐ Musculoskeletal (separate from ALS exam)
- ☐ Neurological
- ☐ Neurologic/CNS
- ☐ Neurological (separate from ALS exam)
- ☐ Oncologic
- ☐ Psychiatric
- ☐ Pulmonary
- ☐ Respiratory
- ☐ Other, specify:

Significant Medical History

[Study Name/ID pre-filled]

Site Name:
Participant ID:

5. *Medical history condition text and corresponding SNOMED CT code
- Verbatim text for the medical condition reported or documented in the medical record as part of medical history:
 - Medical history condition for SNOMED CT code:
6. For each medical condition reported:
- Medical history condition start date and time:
 - Medical history condition ongoing indicator:
☐ Yes
☐ No
☐ Unknown
 - Medical history condition end date and time:
7. Perinatal neurologic event type (Pediatric only):
- ☐ Subarachnoid hemorrhage
 - ☐ Intraparenchymal hemorrhage
 - ☐ Intraventricular hemorrhage
 - ☐ Hypoxia
 - ☐ None
 - ☐ Subdural hemorrhage
 - ☐ Other, specify:

~~Prior traumatic injury indicator:~~

- ☐ ~~Yes~~
- ☐ ~~No~~
- ☐ ~~Unknown~~

~~Prior traumatic injury type:~~

- ☐ ~~Brain Injury~~
- ☐ ~~Spine Injury~~
- ☐ ~~Other Extracranial Injury~~

~~Head injury prior number:~~

~~Blast prior exposure number:~~

Recorder Signature:

Date:

Significant Medical History CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to describe the medical history of the study population relevant to TBI research.

To assess the participant's history of TBI, please use the Ohio State University TBI Identification Method Short Form (OSU TBI-ID), a standardized procedure for eliciting lifetime history of TBI via a structured interview.

Important note: Some of the data elements are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies), as indicated by the asterisk below. The remaining data elements are classified as Supplemental for TBI v3.0, to meet goals for efficient CDE recommendations and because the availability and relevance of medical history data varies by study. While data such as concussion and TBI history are often important to collect, the Supplemental classification of these CDEs emphasizes the need to make study-specific decisions about their collection.

*Element is classified as Disease Core

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

Please see the Data Dictionary for element classifications.

~~Some of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect) or Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below.~~

~~*Element is classified as Core:~~

~~Medical history condition text~~

~~Medical history condition SNOMED CT code~~

~~**Element is classified as Basic for Concussion/Mild TBI studies:~~

~~Concussion prior count~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

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

- Number of lifetime concussions prior to the current injury – Response is obtained from report by participant or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission.
- Source of medical information – Choose all that apply.
- Does the participant have a history of any medical problems/conditions in the following body systems? – Choose one. Response is obtained by participant or proxy report as soon as possible after visit/admission. Document the date the history was obtained so it can be determined whether this information was obtained prior to study enrollment or later. Recommend collection at least on date of TBI or at time of first medical treatment. Comorbidity prior to injury may influence the disease course and chances of recovery. Serious comorbidity or comorbidity that may influence the assessment of outcome are generally considered exclusion criteria in randomized clinical trials. It is therefore highly relevant to accurately record the significant relevant medical history.
- Body system category – Choose one for each medical condition reported. Response is obtained by report of the participant or proxy as soon as possible after visit/admission. Document the date the history was obtained so it can be determined whether this information was obtained prior to study enrollment or later. Recommend collection at least on date of TBI or at time of first medical treatment.

Significant Medical History CRF Module Instructions

Comorbidity prior to injury may influence the disease course and chances of recovery. Serious comorbidity or comorbidity that may influence the assessment of outcome are generally considered exclusion criteria in randomized clinical trials. It is therefore highly relevant to accurately record the significant relevant medical history.

- Body system category other text – Response is obtained by report of the participant or proxy as soon as possible after visit/admission. Document the date the history was obtained so it can be determined whether this information was obtained prior to study enrollment or later. Recommend collection at least on date of TBI or at time of first medical treatment. Comorbidity prior to injury may influence the disease course and chances of recovery. Serious comorbidity or comorbidity that may influence the assessment of outcome are generally considered exclusion criteria in randomized clinical trials. It is therefore highly relevant to accurately record the significant relevant medical history.
- Medical history condition text – Recommend collection at least during initial medical treatment. This element is recommended for pediatric studies.
- Medical history condition SNOMED CT code – Recommend collection at least during initial medical treatment. This element is recommended for pediatric studies.
- Medical history condition start date and time – 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-MM-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.
- Medical history condition ongoing indicator – Choose one.
- Medical history condition end date and time – 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-MM-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.
- Perinatal neurologic event type – Choose all that apply. Response is obtained from report by participant or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission. This element is recommended for pediatric studies. TBI because of the birth process is a common and well-described phenomenon. Presenting symptoms due to birth-related TBI can range from none to severe and include apnea, bradycardia and/or seizures.
- Perinatal neurologic event other text – Response is obtained from report by participant or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission. This element is recommended for pediatric studies. TBI because of the birth process is a common and well-described phenomenon. Presenting symptoms due to birth-related TBI can range from none to severe and include apnea, bradycardia and/or seizures.
- ~~• Prior traumatic injury indicator – Choose one. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission from subject or proxy. This element is recommended for pediatric studies.~~
- ~~• Prior traumatic injury type – Choose all that apply. This element is recommended for pediatric studies.~~
- ~~• Head injury prior number – Response is obtained from report by participant/subject or proxy. Document whether this information was obtained prior to study enrollment or later. Recommend collection as soon as possible after visit/admission.~~
- ~~• Blast prior exposure number – This element should be collected in studies including military populations.~~

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Socioeconomic Status

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. **** Level of education**

What is the highest grade or level of school the participant **subject** has completed, or the highest degree obtained? (Choose one)

- | | |
|--|---|
| <input type="checkbox"/> Never attended/ Kindergarten only | <input type="checkbox"/> High school graduate |
| <input type="checkbox"/> 1st Grade | <input type="checkbox"/> GED or equivalent |
| <input type="checkbox"/> 2nd Grade | <input type="checkbox"/> Some college, no degree |
| <input type="checkbox"/> 3rd Grade | <input type="checkbox"/> Associate degree: occupational, technical, or vocational program |
| <input type="checkbox"/> 4th Grade | <input type="checkbox"/> Associate degree: academic program |
| <input type="checkbox"/> 5th Grade | <input type="checkbox"/> Bachelor's degree (e.g., BA, AB, BS, BBA) |
| <input type="checkbox"/> 6th Grade | <input type="checkbox"/> Master's degree (e.g., MA, MS, MEng, MEd, MBA) |
| <input type="checkbox"/> 7th Grade | <input type="checkbox"/> Professional school degree (e.g., MD, DDS, DVM, JD) |
| <input type="checkbox"/> 8th Grade | <input type="checkbox"/> Doctoral degree (e.g., PhD, EdD) |
| <input type="checkbox"/> 9th Grade | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> 10th Grade | |
| <input type="checkbox"/> 11th Grade | |
| <input type="checkbox"/> 12th Grade, no diploma | |

2. ****Years of education (0-30):**

3. ****Marital/partner status (Choose one):**

- | | |
|--|--|
| <input type="checkbox"/> Never married | <input type="checkbox"/> Separated |
| <input type="checkbox"/> Married | <input type="checkbox"/> Widowed |
| <input type="checkbox"/> Domestic partnership Living with partner | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Divorced | <input type="checkbox"/> Other, specify: |

4. ****What is the participant's current primary occupational status?**

Choose one: If other is selected, please write in response:

- ☐ Paid work (employed/self-employed, including military)
- ☐ Special employment (sheltered workshop, supportive employment, job coach)
 - ☐ Temporary/odd jobs/less than minimum wage jobs
 - ☐ Working less than 20 hours/week, at least minimum wage
 - ☐ Working 20-34 hours/week, at least minimum wage
 - ☐ Working full time (35 hours or more/week, at least minimum wage)
 - ☐ Working, details unknown
- ☐ Only temporarily laid off, sick leave, or ~~maternity~~ parental leave
- ☐ Retired (self-defined)
- ☐ Disabled, permanently or temporarily (self-defined)
- ☐ Student (including on the job training)
- ☐ Homemaker/unpaid caregiver
- ☐ Unemployed, looking for employment (none of the above)
- ☐ Unemployed, not looking for employment (none of the above)
- ☐ Unpaid work (volunteer, internship)
- ☐ Unknown
- ☐ Not applicable (child)
- ☐ Other, specify:

~~*+ Employment status (Choose one):~~

- | | |
|---|--|
| <input type="checkbox"/> Working now | <input type="checkbox"/> Looking for work, unemployed |
| <input type="checkbox"/> Only temporarily laid off, sick leave, or maternity leave | <input type="checkbox"/> Retired |
| | <input type="checkbox"/> Disabled, permanently or temporarily |

Socioeconomic Status

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ ~~Keeping house~~
☐ ~~Student~~

- ☐ ~~Unknown~~
☐ ~~Other, specify:~~

4. ****Job classification category (Choose one):**

- ☐ Officials and managers
☐ Professionals
☐ Technicians
☐ Sales workers
☐ Administrative support workers
☐ Craft workers

- ☐ Operatives
☐ Laborers and helpers
☐ Service workers
☐ ~~Not applicable~~
☐ Unknown
☐ ~~None~~

Additional Core or Basic Pediatric-specific Elements

~~These elements are highly recommended for pediatric studies in addition to the elements above.~~

5. ****Primary caregiver's level of education (Pediatric only):**

What is the ~~parent, guardian, or caregiver's~~ highest grade or level of school ~~the participant's/subject's primary caregiver has completed, or the highest degree obtained~~ completed? (Choose one)

- ☐ Never attended/ Kindergarten only
☐ 1st Grade
☐ 2nd Grade
☐ 3rd Grade
☐ 4th Grade
☐ 5th Grade
☐ 6th Grade
☐ 7th Grade
☐ 8th Grade
☐ 9th Grade
☐ 10th Grade
☐ 11th Grade
☐ 12th Grade, no diploma

- ☐ High school graduate
☐ GED or equivalent
☐ Some college, no degree
☐ Associate degree: occupational, technical, or vocational program
☐ Associate degree: academic program
☐ Bachelor's degree (e.g., BA, AB, BS, BBA)
☐ Master's degree (e.g., MA, MS, MEng, MEd, MBA)
☐ Professional school degree (e.g., MD, DDS, DVM, JD)
☐ Doctoral degree (e.g., PhD, EdD)
☐ Unknown

6. **Primary parent, guardian, or caregiver's years of education (0-30) (Pediatric only):**

7. ~~*School~~ **Participant's school status (Pediatric only):**

- ☐ Going to school
☐ On vacation from school (between grades)
- ☐ Neither
☐ Unknown

Additional Supplemental Elements

~~These elements may be included if relevant to the study. For additional details like permissible values, see the data dictionary associated with this CRF.~~

8. **Education services type (Pediatric only):**

- ☐ Special education
☐ Regular education
☐ None
☐ Unknown
☐ Early intervention

9. **Living with persons number:**

Socioeconomic Status

[Study Name/ID pre-filled]

Site Name:
Participant ID:

10. Living with person relationship type:

- | | | |
|---|--|---|
| <input type="checkbox"/> Alone | <input type="checkbox"/> Military barracks | |
| <input type="checkbox"/> Shared accommodation (independent) | <input type="checkbox"/> In supervised care | |
| <input type="checkbox"/> With spouse/partner | <input type="checkbox"/> Unable to obtain information | |
| <input type="checkbox"/> With children | <input type="checkbox"/> Other, specify: | |
| <input type="checkbox"/> With parents/siblings | | |
| <input type="checkbox"/> Homeless | | |
| | | |
| <input type="checkbox"/> Husband or wife | <input type="checkbox"/> Grandparent | <input type="checkbox"/> Other nonrelative |
| <input type="checkbox"/> Biological son or daughter | <input type="checkbox"/> Parent-in-law | <input type="checkbox"/> Military unit member |
| <input type="checkbox"/> Adopted son or daughter | <input type="checkbox"/> Son-in-law or daughter-in-law | <input type="checkbox"/> N/A — Homeless |
| <input type="checkbox"/> Stepson or stepdaughter | <input type="checkbox"/> Other relative | <input type="checkbox"/> N/A — Alone |
| <input type="checkbox"/> Brother or sister | <input type="checkbox"/> Roomer or boarder | <input type="checkbox"/> Personal care attendant |
| <input type="checkbox"/> Father or mother | <input type="checkbox"/> Housemate or roommate | <input type="checkbox"/> Other patient/ resident in care facility |
| <input type="checkbox"/> Stepfather or stepmother | <input type="checkbox"/> Unmarried partner | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Grandchild | <input type="checkbox"/> Foster child | |

11. Annual household Family income range:

- | | |
|--|--|
| <input type="checkbox"/> Under \$15,000 | <input type="checkbox"/> \$75,000 to \$99,999 |
| <input type="checkbox"/> Less than \$10,000 | <input type="checkbox"/> \$100,000 and over |
| <input type="checkbox"/> \$10,000-\$24,999 | <input type="checkbox"/> \$100,000-\$149,999 |
| <input type="checkbox"/> \$15,000 to \$24,999 | <input type="checkbox"/> \$150,000-\$199,999 |
| <input type="checkbox"/> \$25,000 to \$34,999 | <input type="checkbox"/> \$200,000 or more |
| <input type="checkbox"/> \$35,000 to \$49,999 | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> \$50,000 to \$74,999 | <input type="checkbox"/> Refused to answer |

12. ~~Family income supported persons number~~ What is the number of people supported by the above income?

13. Military service status (Adult only):

- ☐ Active duty military
- ☐ Active reserve (or National Guard)
- ☐ Inactive reserve
- ☐ Retired from military
- ☐ No military service previous or current

14. ~~Military USA~~ U.S. military service branch type (Adult only):

- | | |
|--|--|
| <input type="checkbox"/> Air Force | <input type="checkbox"/> Coast Guard Reserves |
| <input type="checkbox"/> Air Force Reserves | <input type="checkbox"/> Marine Corps |
| <input type="checkbox"/> Air National Guard | <input type="checkbox"/> Marine Corps Reserves |
| <input type="checkbox"/> Army | <input type="checkbox"/> Navy |
| <input type="checkbox"/> Army National Guard | <input type="checkbox"/> Navy Reserves |
| <input type="checkbox"/> Army Reserves | <input type="checkbox"/> Space Force |
| <input type="checkbox"/> Coast Guard | <input type="checkbox"/> Other, specify: |

15. ~~Military USA~~ U.S. military rank category (Adult only):

- ☐ Company grade officer
- ☐ Field grade officer or above
- ☐ Non-commissioned officer (e.g., sergeant/corporal)
- ☐ Warrant officer
- ☐ Other enlisted rank

Socioeconomic Status

[Study Name/ID pre-filled]

Site Name:
Participant ID:

16. Military combat status (Adult only):

- ☐ Combat
☐ Non-combat

17. Military combat zone deployment number (Adult only):

19. Military deployment recency range (Adult only):

- ☐ Less than 3 months
☐ Between 3 and 6 months
☐ Between 6 and 12 months
☐ Greater than 1 year

20. Military combat operations name (Adult only):

- ☐ Desert Storm
☐ Desert Shield
☐ OEF (Operation Enduring Freedom)
☐ OIF (Operation Iraqi Freedom)
☐ Not provided
☐ Other, specify:
☐ Unknown
☐ None

~~Social or voluntary activity type (Adult only)~~

- ☐ ~~Done voluntary or charity work~~
☐ ~~Cared for a sick or disabled adult~~
☐ ~~Provided help to family, friends or neighbors~~
☐ ~~Attended an educational or training course~~
☐ ~~Gone to a sport, social or other kind of club~~
☐ ~~Taken part in a religious organization~~
☐ ~~Taken part in a political or community-related organization~~
☐ ~~None of these~~

21. Health insurance type:

- ☐ Medicaid
☐ Medicare
☐ ~~Employer-sponsored disability insurance~~
☐ Private or group health insurance
☐ National Health Insurance
☐ Veterans Affairs/Military
☐ No insurance
☐ Self-pay
☐ Unknown
☐ Other, specify:

~~†Core or basic for adult only~~

Recorder Signature:

Date:

Socioeconomic Status CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to describe the social status of the study population relevant to TBI research.

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 studies of certain age groups), as indicated by asterisks below. Marital/partner status and current occupational status are recommended for adult studies. Caregiver level of education is recommended for pediatric studies.

****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).

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

Please see the Data Dictionary for element classifications.

~~Important note: Some of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect) or Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below.~~

~~*Element is classified as Core:~~

~~Education year count~~

~~Employment expanded status~~

~~Employment expanded other text~~

~~Education primary caregiver year count~~

~~Education school participation status~~

~~** Element is classified as Basic for Comprehensive, Acute Hospitalized, Concussion/Mild TBI, Moderate/Severe TBI: Rehabilitation or Epidemiology studies:~~

~~Education level USA type~~

~~Education level primary caregiver USA type~~

~~**Element is classified as Basic for Moderate/Severe TBI: Rehabilitation or Epidemiology studies:~~

~~Marital or partner status~~

~~**Element is classified as Basic for Epidemiology studies:~~

~~Job classification category~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

~~The remaining data elements are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

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

- Level of education (Education level USA type) – Choose highest level attained.

Socioeconomic Status CRF Module Instructions

- Years of education – For years completed, ~~after the age of 5~~ starting with 1st grade, code the number of years attained (0–30 years), normed to someone moving full time at the usual pace, i.e., a year that was repeated counts as only 1 year and the usual single-year full-time load completed over several years counts as 1 year. Certificate and technical programs do NOT count no matter how specialized. ~~The number of years of typical completion of the relevant program is counted.~~ To consistently award years based on level of education, number of years aligns with highest level of schooling completed as follows: high school diploma (12 years), associate degree (14 years), bachelor's degree (16 years), master's degree (18 years), one doctoral degree (19-20 years for a 3-4-year doctoral degree, respectively). Post-secondary education that was insufficient to earn a degree will generally fall in between these benchmarks. If the participant obtained their education outside the United States, ask about their educational system to estimate the correct coding – Internship, Residency, and Fellowship years are experiential training and do not count. Recommend collection at least on date of TBI.
- Marital/partner status – Choose one.
- What is the participant's current primary occupational status? – Choose one. May also be useful to record occupational status at time of injury.
- ~~Employment expanded other text – Choose one.~~
- Job classification category – Choose one. Add date stamp for when assessed. Recommend collection at least on date of TBI. Explanations of the categories can be found on the U.S. Equal Employment Opportunity Commission website: <https://www.eeoc.gov/federal-sector/reports/appendix-i-glossary-definitions>
- Primary caregiver's level of education (Education level primary caregiver USA type) – Choose the highest level attained by the participant's primary caregiver.
- Primary parent, guardian, or caregiver's years of education – Record years of education following the same rules as detailed above for participant years of education.
- Participant's ~~Education-school participation~~ status – Choose one. Recommend collection at least on date of TBI.
- Education services type – Choose one.
- Living with persons number – Include everyone who is living or staying here for more than 2 months. Include participant/~~subject~~ if they are living here for more than 2 months. Include anyone else staying here who does not have another place to stay even if they are here for 2 months or less. Do not include anyone who is living somewhere else for more than 2 months, such as college student living away or someone in the Armed Forces on deployment.
- Living with person relationship type – Choose all that apply. Add date stamp for when assessed. Recommend collection at least on date of TBI and perhaps after all initial medical treatment.
- ~~Family~~ Annual household income range – Choose one. This includes pre-tax cash income earned by people, money wages and salaries, self-employment income, property income (dividends, interest and rents), money transfer payments from a variety of government and private welfare and social insurance schemes (such as social security, unemployment and workers' compensation, and public assistance), private and government retirement income, interpersonal transfers (such as alimony and child support) and other periodic income. This excludes certain lump sum payments and capital gains. Add date stamp for when assessed. Recommend collection at least on date of TBI and perhaps after all initial medical treatment.
- ~~Family income supported persons number~~ What is the number of people supported by the above income? – Add date stamp for when assessed. Recommend collection at least on date of TBI and perhaps after all initial medical treatment.
- Military service status – Choose one.
- U.S. military service branch type – Choose one. Response is obtained by report of the participant/~~subject~~ or relatives.
- U.S. military service branch other text – Choose one. Response is obtained by report of the participant/~~subject~~ or relatives.
- U.S. military rank category – Choose one. Response is obtained by report of the participant/~~subject~~ or relatives. NATO rank specifications could be used instead, but military personnel are typically unfamiliar

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with these ranks (i.e., they do not know their own NATO rank specifications). Ranks generally reflect level of responsibility and type of activities engaged in while in theatre - information that may correlate with risk/severity/type of injury.

- Military combat status – Choose one. Response is obtained by report of the participant/~~subject~~ or relatives. Risk of injury, and type/cause of injury are likely to vary by MOS (military occupation) with the greatest risks incurred by those with a combat MOS.
- Military combat zone deployment number – Permissible values should be between 0 - 50, inclusive. Response is obtained by report of the participant/~~subject~~ or relatives. Severity of psychological problems has been shown to correlate with the number of combat deployments.
- Military deployment recency range – Choose one. Response is obtained from report by participant (interview, self-report) or relatives. This element is intended for use in adult military populations.
- Military combat operation name – Choose all that apply.
- ~~• Social voluntary activity type – Choose all that apply.~~
- Health insurance type – Choose one. Document the date the history was obtained so it can be determined whether this information was obtained prior to study enrollment or later. Recommend collection at least on date of TBI and perhaps after all initial medical treatment.

REFERENCES

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National Health and Nutrition Examination Survey (NHANES); National Health Interview Survey (NHIS); PhenX Toolkit (<https://www.phenxtoolkit.org>) Current Educational Attainment #011001

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