

# Headache CDE Revision History Document

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## January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

## July 2017 Revisions

### Overview

There have been significant changes to the content and structure of the Headache CDE materials in Version 2.0 compared to Version 1.0, including the following:

- The number of “Core” CDEs, strongly recommended for all NINDS-funded studies, was reduced;
- The corresponding data dictionaries (i.e., CDE Detail Report) have been modified in accordance with the form changes;
- The Headache CDEs were harmonized with international standardization initiatives and efforts [e.g., International Classification of Headache Disorders-3 (ICHD-3)];
- Every attempt was made to remove duplication and redundancy in the Headache CDEs;

The following case report forms (CRFs) were updated or newly added to the Headache Version 2.0 recommendations.

### New CRFs (4)

Instrument Title	Headache V2.0 Classification
Behavioral History CRF	Supplemental
Magnetoencephalography (MEG) CRF	Supplemental
Cortical Evoked Potentials CRF	Supplemental
Migraine Diagnosis Questionnaire CRF	Supplemental - Highly Recommended

### CRFs Removed (4)

1. Hospitalizations CRF
2. Symptoms, Frequency, and Severity CRF
3. Headache Mail Questionnaire CRF
4. Headache Diagnosis CRF

### Updated CRFs (20)

CDEs were reviewed for accuracy and CDE classifications were modified as needed.

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1. Demographics CRF
2. Social Status CRF
1. Vital Signs CRF
2. Pregnancy Information CRF
3. Pregnancy Outcome CRF
4. Medical and Family History CRF
5. Biomarkers Specimen Collection and Processing CRF
6. DNA Elements CRF
7. Positron Emission Tomography Localization (PET) CRF
8. Quantitative Sensory Testing (QST) CRF
9. Transcranial Magnetic Stimulation (TMS) CRF
10. Anatomical Imaging CRF
11. Nociceptive Blink Reflex and Pain-Related Evoked Potentials CRF
12. Functional Magnetic Resonance Imaging (fMRI) CRF
13. Magnetic Resonance Angiography (MRA) CRF
14. Magnetic Resonance Spectroscopy (MRS) CRF
15. Rescue Treatments CRF
16. Concomitant Medications CRF
17. Headache Calendar CRF
18. Headache Diary – Acute Therapies CRF
19. Headache Diary – Preventive Therapies CRF
20. Medical and Family History Headache / Migraine CRF

The following instruments were recommended or removed. Instrument summaries and classifications were also updated as necessary.

### New Instrument Recommendations (9)

Instrument Title	V2.0 Classification
Functional Impairment Scale (FIS)	Supplemental
ID Migraine Screener	Supplemental - Highly Recommended
Mig S-Cog	Supplemental
Migraine Functional Impact Questionnaire (MFIQ)	Exploratory
Migraine Interictal Burden Scale (MIBS-4)	Supplemental
Migraine Physical Function Impact Diary (MPFID)	Exploratory
Patient Health Questionnaire - 4 (PHQ-4)	Supplemental - Highly Recommended
Patient Global Impression of Change (PGIC)	Exploratory
Structured Diagnostic Interview for Headache (SDIH)	Supplemental

### Instruments Removed (5)

1. Computer-Assisted Telephone Interview (CATI) Headache Diagnostic Telephone Interview
2. CATI Headache Diagnosis Telephone Interview
3. Henry Ford Headache Telephone Claims Interview
4. Visual Aura Rating Scale (VARs)
5. Healthy Days Core Module

### Updated Instrument Recommendations (30)

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Instrument	V1.0 Classification	V2.0 Classification
24 Hour Migraine Quality of Life Questionnaire	Supplemental	Supplemental
Beck Anxiety Inventory	Supplemental	Supplemental
Beck Depression Inventory	Supplemental	Supplemental
Behavior Rating Inventory Executive Function-2 Self Report	Supplemental	Supplemental
Child Depression Inventory 2 (CDI-2)	Supplemental	Supplemental
Clinical Global Impression	Exploratory	Exploratory
Columbia Suicide Severity Rating Scale (C-SSRS)	N/A	Supplemental
EuroQoL-5	Supplemental	Supplemental
Functional Disability Inventory - Child Adolescent Form	Core	Supplemental
Functional Disability Inventory - Parent Form	Core	Supplemental
Generalized Anxiety Disorder (GAD-7)	Supplemental	Supplemental - Highly Recommended
Headache Impact Questionnaire	Exploratory	Exploratory
Headache Impact Test (HIT-6)	Core	Supplemental - Highly Recommended
Headache Needs Assessment Survey (HANA)	Exploratory	Supplemental
Health Related Quality of Life-14 (HRQOL-14)	Exploratory	Exploratory
Hospital Anxiety Depression Scale	Supplemental	Supplemental
Kiddie Schedule for Affective Disorders Schizophrenia	Supplemental	Supplemental
Migraine Specific Quality of Life v.2.1 (MSQoL v2.1)	Core	Supplemental - Highly Recommended
Migraine Disability Assessment Questionnaire (MIDAS)	Supplemental	Supplemental - Highly Recommended
Mini International Neuropsychiatric Interview (MINI)	Supplemental	Supplemental
Mood Disorder Questionnaire	Supplemental	Supplemental
NIH Toolbox	N/A	Supplemental
Patient Health Questionnaire- 9 (PHQ-9)	Supplemental	Supplemental - Highly Recommended
Pediatric Migraine Disability Assessment Questionnaire (PedsMIDAS)	Core	Supplemental - Highly Recommended
Pediatric Quality of Life Inventory (PedsQL)	Supplemental	Supplemental
Patient Reported Outcomes Measurement Information System (PROMIS): Anxiety, Depression ( <i>Adults and Pediatric</i> ), Sleep ( <i>Adult</i> )	N/A	Supplemental

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Instrument	V1.0 Classification	V2.0 Classification
Quality of Life in Neurological Disorders (Neuro-Qol)	N/A	Exploratory
SF-12v2 Short Form Health Survey	Exploratory	Supplemental
SF-36v2 Short Form Health Survey	Supplemental	Supplemental
State Trait Anxiety Inventory	Supplemental	Supplemental
Structured Clinical Interview DSM 5 Disorders Research	Supplemental	Supplemental
International Classification of Headache Disorders (ICHD-3) Criteria	Core	Core

### November 2014 Revisions

- Changes were made to the roster for Headache: Corrected Dr. Timothy Smitherman's name from Timothy Smith in Headache.

### September 2014 Revisions

No changes.

### August 2014 Revisions

- 508-compliant versions of various CRFs, NOCs, Guidelines, Startup and Highlights documents, and other downloadable files posted Headache.

### July 2014 Revisions

No changes.

### June 2014 Revisions

- Corrections to the numbering of the Pregnancy Outcome Form in Headache were included to reduce confusion.

### May 2014 Revisions

No changes.

### April 2014 Revisions

No changes.

### March 2014 Revisions

No changes.

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## February 2014 Revisions

No changes.

## January 2014 Revisions

No changes.

## December 2013 Revisions

- Updated highlight summaries and start-up resource documents for Headache.

## November 2013 Revisions

No changes.

## August 2013 Revisions

### Overview

There have been changes to the content and structure of the Headache CDE materials in Version 2.0 compared to Version 1.0, including the following:

### New Forms:

- Structured Clinical Interview for DSM IV-TR Axis I Disorders Research Version (SCID-I-RV)
- 24 Hour Migraine Quality of Life Questionnaire (24-hr MQoLQ)

### Updated Forms:

Notice of Copyright Created (NOC) (Will replace previously existing forms)

- CATI Headache Diagnosis Telephone Interview
- Henry Ford Headache Telephone Claims Interview
- Visual Aura Rating Scale (VARs)
- Functional Disability Inventory-Child and Adolescent Form (FDI)
- Functional Disability Inventory-Parent Form (FDI)-
- Headache Needs Assessment Survey (HANA)
- Migraine Disability Assessment Test (MIDAS)
- Mini-International Neuropsychiatric Interview (M.I.N.I.)
- Mood Disorder Questionnaire (MDQ)

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- Patient Health Questionnaire (PHQ-9)
- Beck Anxiety Inventory (BAI)
- Beck Depression Inventory (BDI-II)
- Behavior Rating Inventory of Executive Function Self-Report (BRIEF-SR)
- Generalized Anxiety Disorder (GAD-7)
- Hospital Anxiety Depression Scale (HADS)
- State-Trait Anxiety Inventory (STAI)
- Child Depression Inventory 2 (CDI-2)
- Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS)
- Pediatric Migraine Disability Assessment (PedMIDAS)
- Pediatric Quality of Life Inventory (PedsQL)
- 36-Item Short Form Health Survey (SF-36)
- Clinical Global Impression Index (CGI)
- EuroQoL-5 Dimension Questionnaire (EQ-5D)
- Headache Impact Questionnaire (HImQ)
- Headache Impact Test-6 (HIT-6)
- Health Related Quality of Life-14 (HRQOL-14)
- Healthy Days Core Module (CDC-HRQOL-4)
- Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)
- 12 item Short Form Survey (SF-12)

### **Removed Forms:**

### **Detailed Form Revisions:**

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

## Headache CDE Revision History Document

Headache CDE Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Structured Clinical Interview for DSM IV-TR Axis I Disorders Research Version (SCID-I- RV)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
24 Hour Migraine Quality of Life Questionnaire (24-hr MQoLQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
CATI Headache Diagnosis Telephone Interview	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Henry Ford Headache Telephone Claims Interview	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Headache CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Visual Aura Rating Scale (VARS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Functional Disability Inventory-Child and Adolescent Form (FDI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Functional Disability Inventory- Parent Form (FDI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Headache Needs Assessment Survey (HANA)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Migraine Disability Assessment Test (MIDAS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Mini- International Neuropsychiatric Interview (M.I.N.I.)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mood Disorder Questionnaire (MDQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Patient Health Questionnaire (PHQ-9)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beck Anxiety Inventory (BAI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beck Depression Inventory (BDI- II)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Headache CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Behavior Rating Inventory of Executive Function Self- Report (BRIEF- SR)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Generalized Anxiety Disorder (GAD-7)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hospital Anxiety Depression Scale (HADS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
State-Trait Anxiety Inventory (STAI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Child Depression Inventory 2 (CDI- 2)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Migraine Disability Assessment (PedMIDAS)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Quality of Life Inventory (PedsQL)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF-36)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Clinical Global Impression Index (CGI)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
EuroQoL-5 Dimension Questionnaire (EQ-5D)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Headache Impact Questionnaire (HImQ)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Headache Impact Test-6 (HIT-6)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Health Related Quality of Life- 14 (HRQOL-14)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Healthy Days Core Module (CDC-HRQOL-4)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## Headache CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
12 item Short Form Survey (SF- 12)	2.0	1.1	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

### October 2012 Revisions

#### Overview

There have been changes to the content and structure of the Headache CDE materials in Version 1.1 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the Headache CDEs;
- The Headache CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonization (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]
- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and
- The version numbers of many forms (excluding standardized scales/instruments) were updated.
- Several guideline documents were reorganized and consolidated to make it easier to understand which standardized instruments/scales are recommended, though the recommendations themselves remained unchanged.

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- Some of the forms and guideline documents were re-categorized under a different domain or subdomain to be consistent with other NINDS CDEs.
- The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

### Form Status Changes

#### New Forms:

- Physical Exam
- Medical and Family History of Headache/Migraine
- Both of these forms were created using CDEs that were previously included on other forms (i.e., the CDEs on them are not new).

#### Updated Forms:

- Demographics
- Social Status
- Pregnancy Information
- Pregnancy Outcome
- DNA Elements
- Medical and Family History
- Vital Signs
- Biospecimens Collection and Processing Guidelines
- Headache Diagnosis
- Symptoms, Frequency, and Severity
- Hospitalizations
- Headache Diary
- Concomitant Medications
- Headache Record - Acute Therapies
- Headache Record - Preventive Therapies

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### Removed Forms:

- None

### Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response
Various	1.1	1.0	Minor	Modified CDEs	For a number of CDEs, "Unknown" was added to the permissible value set and in some cases "Unknown" replaced "Unknown/Don't Know"
Various	1.1	1.0	Minor	Modified Forms	Instructions were updated to include additional details.
Physical Exam	1.0	1.0	Minor	New Form	Created Physical Exam form using Hand preference type and some additional generic elements from the General CDEs
Demographics	1.1	1.0	Minor	Modified Forms	Relabeled Sex to Gender on form; rearranged CDE order
Demographics	1.1	1.0	Minor	Modified Forms	Added Language primary text, Birth country name, Zip code, and Social security number to form from Social Status form
Demographics	1.1	1.0	Minor	New CDEs	Added Language primary ISO 639-2 code and Birth country ISO 3166-1 alpha-2 code

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Social Status	1.1	1.0	Minor	Modified Forms	Moved Hand preference type, Language primary text, Birth country name, Zip code, and Social security number to other forms
Social Status	1.1	1.0	Minor	Modified Forms	Minor edits to skip logic and footnote
Social Status	1.1	1.0	Minor	Modified CDEs	Modified Employment status and Military USA rank category permissible values
Pregnancy Information	1.0	1.0	Minor	Modified Forms	Edit to footnote
Vital Signs	1.1	1.0	Minor	New CDEs	Added Vital signs date and time
Vital Signs	1.1	1.0	Minor	Modified Forms	Added footnote identifying certain CDEs as Core and made minor change to CDE wording
Vital Signs	1.1	1.0	Minor	Modified CDEs	Changed Temperature measurement anatomic site permissible values
Pregnancy Outcome	1.1	1.0	Minor	Modified Forms	Edit to footnote
Pregnancy Outcome	1.1	1.0	Minor	Modified CDEs	Modified how Birth weight measurement and Gestational age value captured
Pregnancy Outcome	1.1	1.0	Minor	Deleted CDEs	Deleted Date of last menstrual period prior to pregnancy
Medical and Family History of Headache/Migraine	1.1	1.0	Minor	New Form	Form created using CDEs from "Medical and Family History" form
Medical and Family History of Headache/Migraine	1.1	1.0	Minor	New CDEs	Added Family history medical condition first-degree relative type and Family history medical condition second-degree relative type
Medical and Family History	1.1	1.0	Minor	Modified Forms	Moved several CDEs from this form to Medical and Family History of Headache/Migraine. Modified footnote. Modified name of form. Additional minor edits.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Medical and Family History	1.1	1.0	Minor	Modified CDEs	Modified Data source, Family history medical condition type, Body system category permissible values
Medical and Family History	1.1	1.0	Minor	New CDEs	Added Family history medical condition first-degree relative type and Family history medical condition second-degree relative type
Biospecimens Collection and Processing Guidelines	1.1	1.0	Minor	New CDEs	Added Lab specimen collection date and time, Food last consumed date and time, Headache to last headache elapsed time, Headache to sample collection elapsed time, Headache severity prior to sample collection, Medication history change indicator, Premenopausal indicator, Menstrual cycle day at time of collection value, Pregnancy indicator, Pregnancy gestational weeks value, Postpartum indicator, Postpartum days or weeks value, Premenarchal indicator to form
Biospecimens Collection and Processing Guidelines	1.1	1.0	Minor	Modified Forms	Noted that several questions on form serve as guidelines and are not associated with CDEs
Headache Diagnosis	1.1	1.0	Minor	Modified CDEs	Modified Laterality type, Headache frequency, Headache worse during activity indicator, and Headache affected activity level indicator permissible values
Symptoms, Frequency, and Severity	1.0	1.0	Minor	Modified Forms	Minor edits to wording
Headache Diary	1.0	1.0	Minor	Modified Forms	Minor edits to wording

## Headache CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Concomitant Medications	1.0	1.0	Minor	Modified CDEs	Modified Medication prior or concomitant route type permissible values
Headache Record - Acute Therapies	1.0	1.0	Minor	Modified CDEs	Modified Diary date and time, Headache typical pain type, Laterality type, Headache worst pain anatomic site, Headache warning symptom indicator, Headache associated symptom type, Headache typical level activities affected type, Headache post initial study medication date and time, Headache typical severity type, Headache end date and time, Headache went to bed with indicator, Headache re-start date and time , Headache re-start end date and time, Headache worse during activity indicator
Headache Record - Preventive Therapies	1.0	1.0	Minor	Modified CDEs	Modified Headache or migraine date and time, Headache typical pain type, Laterality type, Headache worst pain anatomic site, Headache associated symptom type, Headache affected activity level indicator, Headache worse during activity indicator