**Clinical trial of tinnitus intervention apparatus**

**Case Report Form (Draft)**

Subject Code:

Subject No.:

Research Unit: □ 01 Zhongshan Hospital Affiliated to Fudan University

□

Name of researchers:

Applicant: Zhongshan Hospital Affiliated to Fudan University

version No.: v1.0 Date: August 2, 2020

Vision No. v1.0

Date: July 16,2020

**Instructions for filling out the form**

1.   The medical record report form should be filled in for the qualified and enrolled cases.

2.   Case report forms must be filled out accurately and clearly with a black felt-tip pen.

3.   The participant's report should not be altered when filling in, nor should any record result be cancelled or changed at will during filling in. If there is any mistake, it shall be crossed out with a single line. However, you should keep the original information clearly visible. Fill in the correct information and sign the name or initials of the modifier and the date of amendment.

                 51.5

For example：~~51.0~~Wang Wen，2009-8-14

4.   All subjects replaced their names with initials to protect the privacy of patients. When filling in the abbreviations of patients' names, only the first Pinyin letters of each word in the name should be filled in, and all letters should be capitalized. Those with two-character names should fill in a horizontal line in the middle, those with three-character names should fill in the initial letter of the three-character phonetic alphabet, and those with four-character names should take the initial letter of the first three characters of their names,

For example: The subject's name is Wang Wen, which should be abbreviated to W-W

The subject's name is Wang Xiaowen, which should be abbreviated to W X W

The subject's name is Shangguan Xiaowen, which should be abbreviated to S G X

5.   For the selective question, please mark "×" in the□, such as: ×.

6.   If the inspection items are not checked or missed for some reasons, ND should be filled in. If the inspection is not suitable, fill in NA. If the answer is unknown, write NK.

7.   All dates are listed in order of Year/month/day,2019-06-16.

8.   Adverse event records should be truthfully filled in during the study period. Record the time, severity, duration and measures taken of adverse events. In case of serious adverse events, please timely inform the ETHICS Committee, the person in charge of the research, the sponsor, and the National Medical Products Administration.

(Contact information is as follows)

|  |  |  |  |
| --- | --- | --- | --- |
| Contact unit | contacts | Tel | mailbox |
| Zhongshan Hospital Affiliated to Fudan University | Wu Shuai | 15921977760 | wu.shuai@zs-hospital.sh.cn |
| Research and Evaluation Division of Medical Device Supervision, National Drug Supervision Bureau: 010-88331432 | | | |

9.   The case report form should be filled out strictly according to the requirements of the clinical research program. The items that need to be checked and recorded in different research periods should be carried out according to the Flowchart of the clinical research.

10. The original report form was kept by the researcher, and the copy was kept by Zhongshan Hospital Affiliated to Fudan University.

Case screening

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection Report No.  XX-XXX-XX | Subject No.  □□□ | Subject Name Code  □□□□ | Case Screening |
| Signing Date of Informed Consent | Year/month/day | Signature of Researchers |  |

**Demographic Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Gender | Male / female | Date of Birth |  |
| Nation | Han □, others □, | Occupation |  |

**Physical Examination**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Height | □□□cm | Weight | □□□. □kg | Breathing | □□times / min |
| Heart Rate | □□□times / minute | Blood Pressure | □□□/□□□mmHG | Is there any hearing loss | □Yes □No |

**Currently Suffering from Other Diseases and Medications Besides Hearing Impairment/Tinnitus** N / A

If there are any, please record:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Disease Diagnosis | Date of Diagnosis | Drug Name | Dose | Administration Time | Down Time |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**Screening check**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Project | Specific Projects | Screening Criteria | Yes | | No | |
| Left Ear | Right Ear | Left Ear | Right Ear |
| Imaging Diagnosis | MRI and / or CT | Subjective tinnitus was diagnosed | □ | □ | □ | □ |
| Hearing Diagnosis | Pure Tone Tudiometry | The average pure tone hearing loss at 500,1000, 2000 and 4000 Hz is less than or equal to 70 dB HL | □ | □ | □ | □ |
| Tinnitus Scale | Tinnitus Disability Scale (THI) | THI score > 18 | □ | | □ | |

If the answer to any of the above is No", the patient cannot enter the study.

**Completed by: Signature Date:** Year/month/day

**Inclusion Criteria**

|  |  |  |
| --- | --- | --- |
| Inclusion Criteria | Yes | No |
| Over 14 years of age, male or female | □ | □ |
| Have a full understanding of this study | □ | □ |
| Be able to operate hearing AIDS / tinnitus devices | □ | □ |
| Hearing was stable within 6 months before admission, PTA (0.5-4kh) ≤ 10 dB | □ | □ |
| They were willing to take part in the follow-up within 6 months after fitting hearing AIDS | □ | □ |
| Willing to sign informed consent | □ | □ |
| Didn't participate in any clinical trials in the first three months | □ | □ |

If the answer to any of the above is "No", the patient cannot enter the study.

**Exclusion criteria**

|  |  |  |
| --- | --- | --- |
| Exclusion Criteria | Yes | No |
| Objective tinnitus caused by organic lesions | □ | □ |
| Patients with retrocochlear deafness | □ | □ |
| Ear deformity caused by congenital or traumatic injury |  |  |
| Patients with ear pain and headache | □ | □ |
| Hearing allergy | □ | □ |
| Severe or chronic dizziness | □ | □ |
| Patients with otitis media or external otitis media | □ | □ |
| Patients with eczema of external auditory canal | □ | □ |
| Ear drainage was performed within 90 days | □ | □ |
| There was a history of rapid progressive hearing loss within 90 days | □ | □ |
| Sudden unilateral hearing loss within 90 days | □ | □ |
| Patients with cognitive impairment | □ | □ |
| Patients with psychosomatic disorder | □ | □ |
| Epilepsy patients | □ | □ |
| Patients with severe infectious diseases | □ | □ |
| At the same time, he participated in other similar studies | □ | □ |
| Unable to cooperate with this study | □ | □ |
| The researcher thinks that they are not suitable to participate in this clinical trial | □ | □ |

If the answer to any of the above is "Yes", the patient cannot enter the study.

**Did the patient enter the study?** □Yes □No

**Completed by: Signature Date:** Year/month/day

**Basic information of subjects**

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection Report NO.  XX-XXX-XX | Subject NO.  □□□ | Subject Name Code  □□□□ | Basic Information of Subjects |

Date of obtaining informed consent: mm / DD / yyyy

Gender: Male □ female □

Date of birth: mm / DD / yyyy

**Related medical history**

（1） Results of relevant inspections

Auricle: Left ear: Normal □ Malformations □; Right ear: Normal □ Malformations □

Auditory meatus: Left ear: Normal □ Malformations □; Right ear: Normal □ Malformations □

Tympanic membrane: Left ear: Normal □ Perforation □ Hyperemia □ Invagination □;

Right ear: Normal □ Perforation □ Hyperemia □ Invagination □

History of otologic surgery: Yes □ No □ If yes, please fill in the details

（2） Past disease history

History of infectious diseases: Yes □ No □ If yes, please fill in the details

Other medical history:

（3） Use of hearing aids (If hearing is normal, you do not need to fill in)

Time since the diagnosis of deafness: Year(s)

Whether to wear hearing aids: No □ Yes □ If yes, please fill in the following information:

Ear: Left □ Right □

Matching age: Left ear □ year(s) old, Right ear □ year(s) old

Duration of hearing aid: Left ear □ month(s)； Right ear □ month(s)

Time of wearing hearing aids every day: Left ear □: hour(s)； Right ear □: hour(s)

（4） Tinnitus

Tinnitus side: Left □ Right □

Tinnitus Description: Left ear □ Right ear □

**Completed by: Signature Date:** Year/month/day

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection Report NO.  XX-XXX-XX | Subject NO.  □□□ | Subject Name Code  □□□□ | Case Enrollment |

**Evaluation and follow-up on the day of fitting**

Before wearing Week 0 (- 1-0 days)

**Inspection and evaluation date:**      Year/month/day

**Fill in before fitting:**

1.  Clinical diagnosis:

2.  Hearing test: No hearing loss (0 ~ 20dB) □ Mild (21 ~ 40dB) □ dB

Moderate (41 ~ 60dB) □ dB Severe (61 ~ 80dB) □ dB

3.  Subject questionnaire assessment: Tinnitus Handicap Inventory (THI)

Functionality score: \_\_\_\_\_\_; Critical score: \_\_\_\_\_\_\_;

Emotion score: \_\_\_\_\_\_; Total score: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment Results** | **THI Score** | **Tinnitus Grading** | **Disability Level** |
| □ | 0～16 | first level | No disability |
| □ | 18～36 | second level | Mild disability |
| □ | 38～56 | third level | Moderate disability |
| □ | 58～100 | forth level | Severe disability |

**Fill in after fitting:**

**1、 General condition assessment**

1. Hearing aids are in good condition: Yes □ No □

2. Is there any discomfort: Yes □ No □

3. Hearing aids in good working condition: Yes □ No □

**2、 Events assessment**

If there were any adverse events: Yes □ No □ If yes, please fill in the adverse event form.

If there were any serious adverse events: Yes □ No □ If yes, please fill in the serious adverse event form

**Completed by: Signature Date:** Year/month/day

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection Report NO.  XX-XXX-XX | Subject NO.  □□□ | Subject Name Code  □□□□ | Wearing Stage |

**Follow Up Table**

**The patients were followed up for 2 months**

Date of follow-up: mm / DD / yyyy

Subject contact: Contacted □ Lost □ Reason: \_\_\_\_\_\_\_\_

Type of follow-up: Expected □ Unexpected □ Reason: \_\_\_\_\_\_

**1、 General Condition Assessment**

1. Good wearing condition: Yes □ No □

2. Whether there is discomfort reaction: Yes □ No □

3. Hearing aids in good working condition: Yes □ No □

**2、 Event Assessment**

If there were any adverse events: Yes □ No □ If yes, please fill in the adverse event form.

If there were any serious adverse events: Yes □ No □ If yes, please fill in the serious adverse event form

**3、 Usage**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Serial NO. | Program Settings | Preference Ranking | Average Usage Time Per Day (hours) | Main Use Environment |
| 1 |  |  |  | Family □ Work □ Others: |
| 2 |  |  |  | Family □ Work □ Others: |
| 3 |  |  |  | Family □ Work □ Others: |
| 4 |  |  |  | Family □ Work □ Others: |

**4、 Questionnaire Assessment**

1.  Tinnitus Handicap Inventory (THI)

Functionality score: \_\_\_\_\_\_; Critical score: \_\_\_\_\_\_\_;

Emotion score: \_\_\_\_\_\_; Total score: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment Results** | **THI Score** | **Tinnitus Grading** | **Disability Level** |
| □ | 0～16 | first level | No disability |
| □ | 18～36 | second level | Mild disability |
| □ | 38～56 | third level | Moderate disability |
| □ | 58～100 | forth level | Severe disability |

**Completed by: Signature Date:** Year/month/day

**Follow Up Table**

**The patients were followed up for 6 months**

Date of follow-up: mm / DD / yyyy

Subject contact: Contacted □ Lost □ Reason: \_\_\_\_\_\_\_\_

Type of follow-up: Expected □ Unexpected □ Reason: \_\_\_\_\_\_

**1、 General Condition Assessment**

1. Good wearing condition: Yes □ No □

2. Whether there is discomfort reaction: Yes □ No □

3. Hearing aids in good working condition: Yes □ No □

**2、 Event Assessment**

If there were any adverse events: Yes □ No □ If yes, please fill in the adverse event form.

If there were any serious adverse events: Yes □ No □ If yes, please fill in the serious adverse event form

**3、 Usage**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Serial NO. | Program Settings | Preference Ranking | Average Usage Time Per Day (hours) | Main Use Environment |
| 1 |  |  |  | Family □ Work □ Others: |
| 2 |  |  |  | Family □ Work □ Others: |
| 3 |  |  |  | Family □ Work □ Others: |
| 4 |  |  |  | Family □ Work □ Others: |

**4、 Questionnaire Assessment**

1.  Tinnitus Handicap Inventory (THI)

Functionality score: \_\_\_\_\_\_; Critical score: \_\_\_\_\_\_\_;

Emotion score: \_\_\_\_\_\_; Total score: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment Results** | **THI Score** | **Tinnitus Grading** | **Disability Level** |
| □ | 0～16 | first level | No disability |
| □ | 18～36 | second level | Mild disability |
| □ | 38～56 | third level | Moderate disability |
| □ | 58～100 | forth level | Severe disability |

**Completed by: Signature Date:** Year/month/day

**Tinnitus Handicap Inventory, THI**

|  |
| --- |
|  |
|  | The purpose of the scale is to help you identify problems that tinnitus may cause to you. Please choose yes, no, or sometimes. Don't skip any questions. |

The problem description is sometimes not

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Items | Answer | | |
| Yes | Sometimes | No |
| 1F | Does tinnitus make it difficult for you to concentrate? | □ | □ | □ |
| 2F | Does tinnitus affect your ability to listen to other people's voices? | □ | □ | □ |
| 3E | Does the tinnitus make you angry? | □ | □ | □ |
| 4F | Does tinnitus confuse you? | □ | □ | □ |
| 5C | Does tinnitus make you feel desperate? | □ | □ | □ |
| 6E | Do you often complain about tinnitus? | □ | □ | □ |
| 7F | Does tinnitus affect your sleep? | □ | □ | □ |
| 8C | Do you think you can't get rid of tinnitus? | □ | □ | □ |
| 9F | Does tinnitus affect your enjoyment of social activities? (For example, eating out, watching movies, etc.) | □ | □ | □ |
| 10E | Does tinnitus make you feel frustrated? | □ | □ | □ |
| 11C | Does tinnitus make you feel seriously ill? | □ | □ | □ |
| 12F | Does tinnitus affect your enjoyment of life? | □ | □ | □ |
| 13F | Does tinnitus interfere with your work or family responsibilities? | □ | □ | □ |
| 14E | Does tinnitus make you irritable? | □ | □ | □ |
| 15F | Does tinnitus affect your reading? | □ | □ | □ |
| 16E | Does tinnitus depress you? | □ | □ | □ |
| 17E | Do you think tinnitus makes you tense with your family and friends? | □ | □ | □ |
| 18F | Is it hard not to think about tinnitus and do something else? | □ | □ | □ |
| 19C | Do you think you can't control tinnitus? | □ | □ | □ |
| 20F | Does tinnitus make you tired? | □ | □ | □ |
| 21E | Does tinnitus make you feel depressed? | □ | □ | □ |
| 22E | Does tinnitus make you feel anxious? | □ | □ | □ |
| 23C | Do you feel that you can no longer tolerate tinnitus? | □ | □ | □ |
| 24F | Does tinnitus increase when you are stressed? | □ | □ | □ |
| 25E | Does tinnitus make you insecure? | □ | □ | □ |

|  |
| --- |
|  |
|  | Functionality score: \_\_\_\_\_\_; Critical score: \_\_\_\_\_\_\_;  Emotion score: \_\_\_\_\_\_; Total score: \_\_\_\_\_\_\_ |

Note: F—Functionality E—Emotion C—Critical

**Record of Adverse Events**

|  |  |  |
| --- | --- | --- |
| Name of Adverse Event |  |  |
| Specific Description of Adverse Events |  |  |
| Time of Occurrence | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock |
| End time | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock |
| Degree | Light □ Medium □ Heavy □ | Light □ Medium □ Heavy □ |
| Reversion | □ Remission  □ Sequelae  □ Continuing  □ Death | □ Remission  □ Sequelae  □ Continuing  □ Death |
| Relationship with Surgery | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment |
| Relationship with Test Apparatus System | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment |
| Corrective treatment | □No □ Yes  If so, please record: | □No □ Yes  If so, please record: |
| Is it a serious adverse event | □No □ Yes | □No □ Yes |
| Whether to withdraw due to adverse events  Experiment | □No □ Yes | □No □ Yes |

**Completed by: Signature Date:** Year/month/day **Record of Adverse Events**

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection Report NO.  XX-XXX-XX | Subject NO.  □□□ | Subject Name Code  □□□□ | Adverse Event Report Form |

|  |  |  |
| --- | --- | --- |
| Name of Adverse Event |  |  |
| Specific Description of Adverse Events |  |  |
| Time of Occurrence | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock |
| End time | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock |
| Degree | Light □ Medium □ Heavy □ | Light □ Medium □ Heavy □ |
| Reversion | □ Remission  □ Sequelae  □ Continuing  □ Death | □ Remission  □ Sequelae  □ Continuing  □ Death |
| Relationship with Surgery | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment |
| Relationship with Test Apparatus System | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment |
| Corrective treatment | □No □ Yes  If so, please record: | □No □ Yes  If so, please record: |
| Is it a serious adverse event | □No □ Yes | □No □ Yes |
| Whether to withdraw due to adverse events  Experiment | □No □ Yes | □No □ Yes |

**Completed by: Signature Date:** Year/month/day

**Record of Adverse Events**

|  |  |  |
| --- | --- | --- |
| Name of Adverse Event |  |  |
| Specific Description of Adverse Events |  |  |
| Time of Occurrence | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock |
| End time | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock | │▁│▁│▁│▁│ year│▁│▁│ month│▁│▁│ day│▁│▁│ clock |
| Degree | Light □ Medium □ Heavy □ | Light □ Medium □ Heavy □ |
| Reversion | □ Remission  □ Sequelae  □ Continuing  □ Death | □ Remission  □ Sequelae  □ Continuing  □ Death |
| Relationship with Surgery | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment |
| Relationship with Test Apparatus System | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | □ Certainly  □ Probably related  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment |
| Corrective treatment | □No □ Yes  If so, please record: | □No □ Yes  If so, please record: |
| Is it a serious adverse event | □No □ Yes | □No □ Yes |
| Whether to withdraw due to adverse events  Experiment | □No □ Yes | □No □ Yes |

**Completed by: Signature Date:** Year/month/day **Serious Adverse Events**

Whether serious adverse events occur during clinical verification: □ Yes □ No If yes, please fill in the serious adverse event record form

Name of the serious adverse event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| Report Type | □ First Report □ Follow Up Report □ Summary Report | | Time of report: mm / DD / yyyy |
| Situation of SAE | □ Leading to hospitalization □ Extended hospital stay □ Disability □Dysfunction □ Cause congenital malformations □Life threatening or death □ Others | | |
| Time of SAE: mm / DD / yyyy | | Severity of SAE response:   □Mild □ Moderate □ Severe | |
| SAE Outcome | □ Symptoms Disappeared (Sequelae □ Yes □ No) Time to disappear: mm / DD / yyyy  □ Symptoms Persist  □ Death (Time of Death: mm / DD / yyyy) | | |
| The relationship between SAE and the whole system of test instruments | □ Certainly  □ It may be relevant  □ Maybe not  □ It has nothing to do with it  □ No judgment | | |
| SAE Report | Domestic: □ Yes □ No □ Unknown foreign: □ Yes □ No □ Unknown | | |
| Details of SAE Occurrence and Treatment: | | | |
|  |  |  |  |

**Completed by: Signature Date:** Year/month/day

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection Report NO.  XX-XXX-XX | Subject NO.  □□□ | Subject Name Code  □□□□ | Summary and Evaluation |

**Completion of the Study**

**1. Evaluation criteria and conclusions of the study**

|  |  |
| --- | --- |
| First matching date of subjects: | Year/month/day |
| Date of last follow-up: | Year/month/day |
| Did the subjects have any adverse events during the study | No □ Yes □ |
| Did the patients complete the clinical study on time? No □ Yes □  If not, please fill in the following items:  The date on which the patient stopped participating in the study: mm / DD / yyyy | |
| The first to stop the study was: (please choose one)  Subject □ Researcher □ Sponsor □ Other reasons (please specify) | |
| The main reasons for stopping the study were: (please choose one)  Adverse events (completed adverse event form) □ Lack of efficacy □ Violation of test protocol □  Informed consent was withdrawn by subjects □ Lost to follow-up □ Study discontinuation □  Other reasons (please specify) | |
| Others: | |

**2.** **Tinnitus Handicap Inventory (THI)**

Before wearing:

Functionality score: \_\_\_\_\_\_; Critical score: \_\_\_\_\_\_\_;

Emotion score: \_\_\_\_\_\_; Total score: \_\_\_\_\_\_\_

After wearing:

Functionality score: \_\_\_\_\_\_; Critical score: \_\_\_\_\_\_\_;

Emotion score: \_\_\_\_\_\_; Total score: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment Results** | **THI Score** | **Tinnitus Grading** | **Disability Level** |
| □ | 0～16 | first level | No disability |
| □ | 18～36 | second level | Mild disability |
| □ | 38～56 | third level | Moderate disability |
| □ | 58～100 | forth level | Severe disability |

**Completed by: Signature Date:** Year/month/day

|  |  |  |  |
| --- | --- | --- | --- |
| Inspection report NO.  XX-XXX-XX | Subject NO.  □□□ | Subject Name Code  □□□□ | GRF  Audit Statement |

**Statement on Review of CRF Case Report Form**

**The person in charge of the research center hereby declares that this case report form has been reviewed by the project leader of the clinical research unit and the supervisor of the bidding unit. All items filled in are true, complete and accurate.**

Signature of the person in charge of the bidding unit

Date of signature: mm / DD / yyyy

Signature of the person in charge of the research center

Date of signature: mm / DD / yyyy

Research flow chart

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Stage | | Screen | Joining the Group | Wearing and Visiting Stage |
| Time | | 0Week (- 1-0 days) | 0Week (0 days) | 6Weeks (± 3 days) |
| Sign Informed Consent | | √ |  |  |
| Demographic Data | | √ |  |  |
| Entry Audit | Researcher Assessment |  | √① |  |
| Subject Questionnaire |  | √② |  |
| Matching tinnitus frequency and loudness | |  | √ |  |
| Monitoring the wearing process | |  |  | √ |
| Record combined drugs / devices | |  |  | √ |
| Recording adverse events | |  |  | √ |
| Safety evaluation | |  |  | √ |
| Efficacy evaluation | Researcher assessment |  |  | √③ |
| Subject questionnaire |  |  | √④ |
| Study director reviews medical records | |  |  | √ |
| The supervisor reviews the medical record | |  |  | √ |

①Including hearing assessment, tinnitus loudness and tinnitus frequency matching test;

②Tinnitus Handicap Inventory (THI), Tinnitus Reaction Questionnaire (TRQ);

③ Including hearing threshold test;

④ Tinnitus Handicap Inventory (THI), Tinnitus Reaction Questionnaire (TRQ)