# APPENDIX

# A Information assessed prior to study inclusion

# A1. Questionnaires to be completed by the participant-

**A1.1. - PART 1: *Questionnaire about the participant’s state of health***

**A1.1. – PART 2: *Questionnaire about the participant’s state of health – TEMPLATE FOR THE INVESTIGATOR***

**2. Questionnaires to be completed by the investigator -**

**A2.1. *Screening checklist for healthy subjects***

**B Information assessed after study inclusion**

**B1. Questionnaires to be completed by the investigator**

***Questionnaire for healthy subjects***

**B2. Questionnaires to be completed by the participant**

***MOTIVATIONS AND EXPECTATIONS***

**Name/ ID: Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. In the past 3 months have you suffered from strong pain, lasting for more than 24 hours?

□ no

□ yes, on less than 3 days

□ yes, on more than 3 days

1. If yes, what was the reason for your pain multiple answers possible):

□ trauma □ headache

□ operation □ back pain

□ pain during a flue □ stomach ache

□ menstrual pain □ painful joints

□ alcohol consumption („hangover“) □ neuralgia

□ injury/ aching muscles after sports

□ other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. In the last 3 months have you taken medication for your pain?

□ no

□ yes, less than 3 tablets/ month

□ yes, 4-10 tablets/ month

□yes, more than 10 tablets/ month

1. If yes, what was the reason for your medication multiple answers possible):

□ trauma □ headache

□ operation □ back pain

□ pain during a flue □ stomach ache

□ menstrual pain □ painful joints

□ alcohol consumption („hangover“) □ neuralgia

□ injury/ aching muscles after sports

□ other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Have you ever (more than 3 months ago) suffered from diseases accompanied by long lasting pain for longer than 3 months?

□ no □ yes

1. If yes, what was the reason for your pain (multiple answers possible):

□ trauma □ headache

□ operation □ back pain

□ pain during a flue □ stomach ache

□ menstrual pain □ painful joints

□ alcohol consumption („hangover“) □ neuralgia

□ injury/ aching muscles after sports

□ other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How long ago did this happen?

□ 3-12 months ago

□ 1-3 years ago

□ 3-5 years ago

□ 5-10 years ago

□ more than 10 years ago

1. Have you sought professional help for your pain from a doctor, holistic therapist, psychiatrist/ psychotherapist, physiotherapist or chiropractor etc during the last 3 years?

□ no □ yes

1. In the past 5 years, have you had any psychological or psychiatric treatment?

□ no □ yes, only for a short time □ yes, for a longer period

1. How often have you been signed off work due to pain in the last 3 years?

□ not applicable (i.e. retired or not actively working)

□ never

□ only a couple of days overall (max. 7 days)

□ once (duration max. 7 days)

□ more frequently

1. Do you smoke?

□ no □ yes □ not at the moment, but I used to smoke

* 1. If yes, how much? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for how many years? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  2. not at the moment, but I used to smoke, when did you quit? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How often and how much do you drink alcohol?

□ never □ regularly, moderate amount

□ occasionally, moderate amount □ regularly, a lot

□ occasionally, a lot □ often, beyond the proper amount

a. Please specify (on average) how much alcohol you drink (glasses or bottles/per week):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How do you consider your behaviour concerning the intake of medication (except contraceptives)?

□ I never take any medication

□ I rarely take medication

□ I often take medication

□ I take medication too often

a. Which medication in what dosage have you taken **in the last 4 weeks** on demand or on a regular basis on prescription, over the counter and homeopathic/ herbal medication? Please list all.

1.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_3.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_4.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_5.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_6.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_7.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_8.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_9.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The table below lists groups of disorders according to the different organ systems including some examples for that kind of disorders. Do you currently or did you in the past suffer from any of these or related disorders? Please mark any that apply to you. Please also indicate how much this disorder **currently** interferes with your everyday life 0 = no interference, 3 = high degree of interference).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Tumor, cancer** Please specify: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the nervous system, brain, or spinal cord** e.g. epilepsy, MS, Parkinson’s disease, nerve injury, polyneuropathy, spinal cord injury, paralysis, neuralgia, stroke, cranial nerve injury  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the respiratory system** e.g. Asthma, chronic bronchitis, emphysema, pneumothorax, tuberculosis or inflammation of the lungs  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the heart or circulatory system** e.g.Coronary heart disease, arrhythmia, thrombosis, embolism, aneurysm, high blood pressure, myocardial infarction  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Gastrointestinal disorder** e.g. Gastric reflux disorder, Crohn's disease, ulcerative colitis, haemorrhoids, incontinence of faeces, duodenal ulcers, irritable bowel syndrome, incidence of stomach or intestinal haemorrhage  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the liver, gall bladder or pancreas** e.g. chronic inflammation of the liver =hepatitis, cirrhosis of the liver, gall stones, gall bladder inflammation, pancreatic inflammation  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the kidneys or urogenital system** e.g. chronic kidney failure, urinary tract inflammation, bladder weakness, endometriosis, condition following renal colic or kidney stones, sexual disturbance  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Metabolic disorder** e.g. Disrupted sugar metabolism, diabetes, hyper- or hypo- glandular function, hyperlipidaemia  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Musculoskeletal disorder** e.g. Chronic polyarthritis, rheumatic muscular inflammation, scoliosis, osteoporosis, arthritis  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Mental health disorder** e.g. Depression, anxiety, panic attacks, eating disorders, chronic fatigue and exhaustion, addiction or substance dependence, psychosis  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Other disorders or conditions:** | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Risk factors** e.g. Haemophilia, hepatitis, HIV  Other: | □ yes □ no | | | | | |
| **Allergies** | □ yes □ no | | | | | |

**Instructions for the investigator:** The grey marked answers in the template are not definitive exclusion criteria. However, the investigator should check again by an extensive exploration and an extensive clinical neurological/ internal examination and upon this basis to carefully decide whether the subject might nevertheless be enrolled in the study as a “healthy subject.

1. In the past 3 months have you suffered from strong pain, lasting for more than 24 hours?

□ no

□ yes, on less than 3 days

□ yes, on more than 3 days

1. If yes, what was the reason for your pain multiple answers possible):

□ trauma □ headache

□ operation □ back pain

□ pain during a flue □ stomach ache

□ menstrual pain □ painful joints

□ alcohol consumption („hangover“) □ neuralgia

□ injury/ aching muscles after sports

□ other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. In the last 3 months have you taken medication for your pain?

□ no

□ yes, less than 3 tablets/ month

□ yes, 4-10 tablets/ month

□ yes, more than 10 tablets/month

1. If yes, what was the reason for your medication (multiple answers possible):

□ trauma □ headache

□ operation □ back pain

□ pain during a flue □ stomach ache

□ menstrual pain □ painful joints

□ alcohol consumption („hangover“) □ neuralgia

□ injury/ aching muscles after sports

□ other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Have you ever (more than 3 months ago) suffered from diseases accompanied by long lasting pain for longer than 3 months)?

□ no □ yes

If yes:

1. If yes, what was the reason for your pain (multiple answers possible):

□ trauma □ headache

□ operation □ back pain

□ pain during a flue □ stomach ache

□ menstrual pain □ painful joints

□ alcohol consumption („hangover“) □ neuralgia

□ injury/ aching muscles after sports

□ other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How long ago did this happen?

□ 3-12 months ago

□ 1-3 years ago

□ 3-5 years ago

□ 5-10 years ago

□ more than 10 years ago

1. Have you ever sought professional help for your pain from a doctor, holistic therapist, psychiatrist/ psychotherapist, physiotherapist or chiropractor etc?

□ no □ yes

1. In the past 5 years have you had any psychological or psychiatric treatment?

□ no □ yes, only for a short time □ yes, for a longer period

1. How often have you been signed off work due to pain in the last 3 years?

□ not applicable (i.e. retired or not actively working)

□ never

□ only a couple of days overall (max. 7 days)

□ once (duration max. 7 days)

□ more frequently

1. Do you smoke?

□ no □ yes □ not at the moment, but I used to smoke

1. If yes, how much? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for how many years? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. not at the moment, but I used to smoke, when did you quit? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instructions for the investigator:** If the subject smokes more than 39 cigarettes per day, she/ he should be excluded.

1. How often and how much do you drink alcohol?

□ never □ regularly, moderate amount

□ occasionally, moderate amount □ regularly, a lot

□ occasionally, a lot □ often, beyond the proper amount

a. Please specify on average) how much alcohol you drink glasses or bottles/per week)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. How do you consider your behaviour concerning the intake of medication (except contraceptives)

□ I never take any medication

□ I rarely take medication

□ I often take medication

□ I take medication too often

1. Which medication in what dose have you taken **in the last 4 weeks** on demand or on a regular basis on prescription, over the counter and homeopathic/ herbal medication? Please list all.

**Instructions for the investigator:** Regular intake of St. John’s wort, psychostimulants or any other regular medication (except contraceptives) on therapeutic purposes are exclusion criteria.

1. The table below lists groups of disorders according to the different organ systems including some examples for that kind of disorders. Do you currently or did you in the past suffer from any of these or related disorders? Please mark any that apply to you. Please also indicate how much this disorder **currently** interferes with your everyday life 0 = no interference, 3 = high degree of interference).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Tumour, cancer** Please specify: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the nervous system, brain, or spinal cord** e.g. epilepsy, MS, Parkinsons`disease, nerve injury, polyneuropathy, spinal cord injury, paralysis, neuralgia, stroke, cranial nerve injury)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the respiratory system** e.g. Asthma, chronic bronchitis, emphysema, pneumothorax, tuberculosis or inflammation of the lungs)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the heart or circulatory system** e.g.Coronary heart disease, coronary arrhythmia, thrombosis, embolism, aneurysm, high blood pressure, myocardial infarction)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Gastrointestinal disorder** e.g. Gastric reflux disorder, Crohn's disease, ulcerative colitis, haemorrhoids, incontinence of faeces, duodenal ulcers, irritable bowel syndrome, incidence of stomach or intestinal haemorrhage)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the liver, gall bladder or pancreas** e.g. chronic inflammation of the liver =hepatitis), cirrhosis of the liver, gall stones, gall bladder inflammation, pancreatic inflammation)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Disorder of the kidneys or urogenital system** e.g. chronic kidney failure, urinary tract inflammation, bladder weakness, endometriosis, condition following renal colic or kidney stones, sexual disturbance)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Metabolic disorder** e.g. Disrupted sugar metabolism, diabetes, hyper- or hypo- glandular function, hyperlipidaemia)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Musculoskeletal disorder** e.g. Chronic polyarthritis, rheumatic muscular inflammation, scoliosis, osteoporosis, arthritis)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Mental health disorder** e.g. Depression, anxiety, panic attacks, eating disorders, chronic fatigue and exhaustion, addiction or dependence, psychosis)  Other: | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Other disorders or conditions:** e.g. hepatitis, HIV)  Other:**:** | □ yes □ no | | | | | |
| No | | Interference | | High degree | |
| [0] | [1] | | [2] | | [3] |
| **Allergies** | □ yes □ no | | | | | |

**Name/ ID: Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ If the answer to one of the following questions is “yes”, the subject cannot be included in the study as a „healthy subject“. Exceptions from this norm are answers to questions marked with “#” where the inclusion needs to be postponed until further evaluation or examinations have been made by the investigator.**

|  |  |  |
| --- | --- | --- |
| **General information** | **yes** | **no** |
| 1. Person younger than 18 years | □ | □ |
| 1. Missing informed consent form | □ | □ |
| 1. Insufficient language skills (for non-native speakers) | □ | □ |
| 1. Participation in a drug trial <30days before inclusion in the present study | □# | □ |
| 1. Jet lag / irregular working hours / sleep restriction in the last 3 days | □# | □ |
| 1. Changes in physical exercise activities e.g. starting workout/ training within 1 week prior to the study | □# | □ |
| **Current and past medical history** |  |  |
| 1. Current pain | □ | □ |
| 1. Pain in the last 14 days | □# | □ |
| 1. Radiculopathy with long-lasting pain in the last 3 months | □ | □ |
| 1. Long-lasting local back pain on more than 5 days/ month in the last 3 months | □ | □ |
| 1. Migraine (minimum 1 attack in the last 24 months) | □ | □ |
| 1. Recurrent headache (on more than 5 days/ month in the last 3 months) | □ | □ |
| 1. History of severe internal diseases (e.g. diabetes mellitus, liver diseases, kidney diseases, cardiovascular diseases, hypo- or hyperthyroidism, hypertension etc.) | □ | □ |
| 1. Chronic dermal diseases including the testing area | □ | □ |
| 1. History of central neurological diseases (e.g. cerebral insults, multiple sclerosis, Parkinson disease) | □ | □ |
| 1. Polyneuropathy | □ | □ |
| 1. Peripheral nerve lesion in one of the testing areas | □ | □ |
| 1. Manifest psychiatric diseases (e.g. depression) | □ | □ |
| 1. Intake of analgesic medication incl. paracetamol/ acetaminophen, acetylsalicylic acid, other NSAID etc.) within the last 14 days # | □ | □ |
| 1. Intake of triptans in the last 24 months | □ | □ |
| 1. Intake of drugs with psycho-/ neuropharmacological effects in the last 3 months | □ | □ |
| 1. Any regular medication, inclusive St. Johns wort or other psychostimulants except contraceptives) | □ | □ |
| 1. Use of any prescription or nonprescription drugs (except contraceptives) within 7 days or 5 half-lives (whichever is longer) prior to the study | □# | □ |
| 1. History of abuse of alcohol or other drugs (as defined by ICD-10 or DSM IV) | □ | □ |
| 1. Consume of illegal drugs, including cannabis in the last 4 weeks prior to the study | □# | □ |
| 1. Alcohol consume or consume of energy drinks like red bull or alike in the last 48 hours prior to the study | □# | □ |
| **Bedside-screening tests for polyneuropathy** |  |  |
| 1. Achilles' tendon reflex absent or abnormally diminished or increased compared to the contralateral side | □ | □ |
| 1. Vibration detection threshold <5/8 for subjects younger than 60 years (resp. < 4/8 for subjects aged 60 years and older) over the medial malleolus | □ | □ |

**Also, check the answers in the questionnaire about the participant’s state of health**

which was completed by the participant on the:\_\_\_\_\_\_\_\_\_\_\_\_\_)

**Problematic answers in the questionnaire** **about the participant’s state of health)?**

□ yes □ no

**If YES,** problematic answers to question No.:

□ **1** □ **2** □ **3** □ **4** □ **5** □ **6 □ 7**

□ **8** □ **9** □ **10**

**Please write down the reasons why the participant can be included in the study as a healthy subject nevertheless (free text):**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Summary I:**

|  |  |  |
| --- | --- | --- |
| **Recruitment as a healthy subject?** | □ yes | □ no |

Please point out that the participant should not:

* take any pain medication 14 days before the QST.
* use any prescription or nonprescription drugs (except contraceptives) within 7 days or 5 half-lives (whichever is longer) prior to QST

Changes in the medication as well as newly occurred pain must be communicated to the investigator prior to QST.

**Analysis of the QST parameter of the first examination**

In case of any abnormal QST results (z-value > 1,96 or < -1,96), an extensive clinical internal/ neurological examination is necessary.

**Please mark:**

□ QST within the normal range

□ QST results abnormal, if yes which parameters: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If the QST z-values are >1,96 or <-1,96, write down the reasons why the participant can be included in the study as a healthy subject nevertheless (free text):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
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**Summary II:**

|  |  |  |
| --- | --- | --- |
| **Inclusion into the study?** | □ yes | □ no |

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**General questions**

1. Age: \_\_\_ years 2. Height: \_\_\_\_\_\_\_\_ cm 3. Weight: \_\_\_\_\_\_ kg

1. Sex: □ male □ female
2. Native language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Ethnic background: □ White □ Black □Asian □ other:\_\_\_\_\_\_\_\_\_\_\_
4. Level of speech comprehension

□ very good □ good □sufficient □ not sufficient

1. Mode of recruitment:

□ co-worker of the investigator or working in a related department

□ staff from other departments of the hospital etc.

□ student

□ relative or friend of investigator or co-worker

□ via advertisement

□ other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is there any reimbursement for the participation in the trial/ experiment?

□ no

□ only travel costs

□ fixed sum: □ less than 100 Euro □ more than 100 Euro

1. Prior experience with trials or experiments:

□ no

□ 1-3 trials/ experiments within the last 3 years

□ more than 3 trials/ experiments within the last 3 years

□ more than 3 trials/ experiments years ago

1. Education:

□ no school graduation

□ school graduation without qualification for university entrance

□ school graduation with qualification for university entrance

□ completed apprenticeship

□ graduation from university

□ not available

1. Current status:

□ student □ [self-employed](http://dict.leo.org/ende?lp=ende&p=5tY9AA&search=self-employed)

□ graduate student □ medicine, □ psychology, □ other) □ unemployed

□ employee □ housewife/ house-husband

□ executive function/ manager □ other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

□ not available

1. Field of activity:

□ medical care □ other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

□ medical research □ unemployed at the moment

□ not available

**Motivation and expectations**

1. How important were the following reasons for you to consider participating in the present trial/ experiment? Please circle the appropriate number 0 = „not important at all“ to 6 = „very important“, n.a. = „I don’t know/not available“).

To support science 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

To support the investigator 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Interest in the aim of the study 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Possible improvement for treatment of patients 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Financial reasons 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

To have something to do 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Curiosity 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

To have social contacts/being part of a team 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

To find out more about general health 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

To get a health check-up 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Other reasons:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

1. In your opinion, which is the aim of the present study/ experiment/ trial?  
   0 = „not correct at all“ to 6 = „fully correct“, n.a. = „I don’t know/not available“)

Research about the skin sensitivity 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Research about pain thresholds 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Research about influence of medication 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

Other aims:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

1. How well were you informed about the aims of the present study/ experiment/ trial?

0 = „not at all“ to 6 = „very well“, n.a. = „I don’t know/not available“)

0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

1. How well were you informed about the course of the present study/ experiment/ trial?

0 = „not at all“ to 6 = „very well“, n.a. = „I don’t know/not available“)

0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

1. Do you feel worried or are you afraid of feeling pain during the present study/ experiment/ trial?

0 = „not afraid at all“ to 6 = „very much afraid“, n.a. = „I don’t know/not available“)

0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.

1. Do you feel worried or are you afraid of other possible consequences during the present study/ experiment/ trial?

0 = „not afraid at all“ to 6 = „very much afraid“, n.a. = „I don’t know/not available“)

0 - 1 - 2 - 3 - 4 - 5 - 6 □ n.a.