Beta-Medical research facilities FSW

Policies, protocols and guidelines

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Introduction

Various rooms within the Faculty of Social and Behavioural Sciences (FSW) in the Pieter de la Court building (first floor and basement) have been set up as laboratories for beta-medical research. In order to ensure these laboratories are used safely and efficiently by researchers and participants, the faculty has had some regulations drawn up. Below you will find an overview of the policy, the regulations, and the guidelines.

This document has been created with input from the Natural Sciences Policy committee, the lab coordinators, and many others.

Contents

Overview (how many, where, and for what type of research)

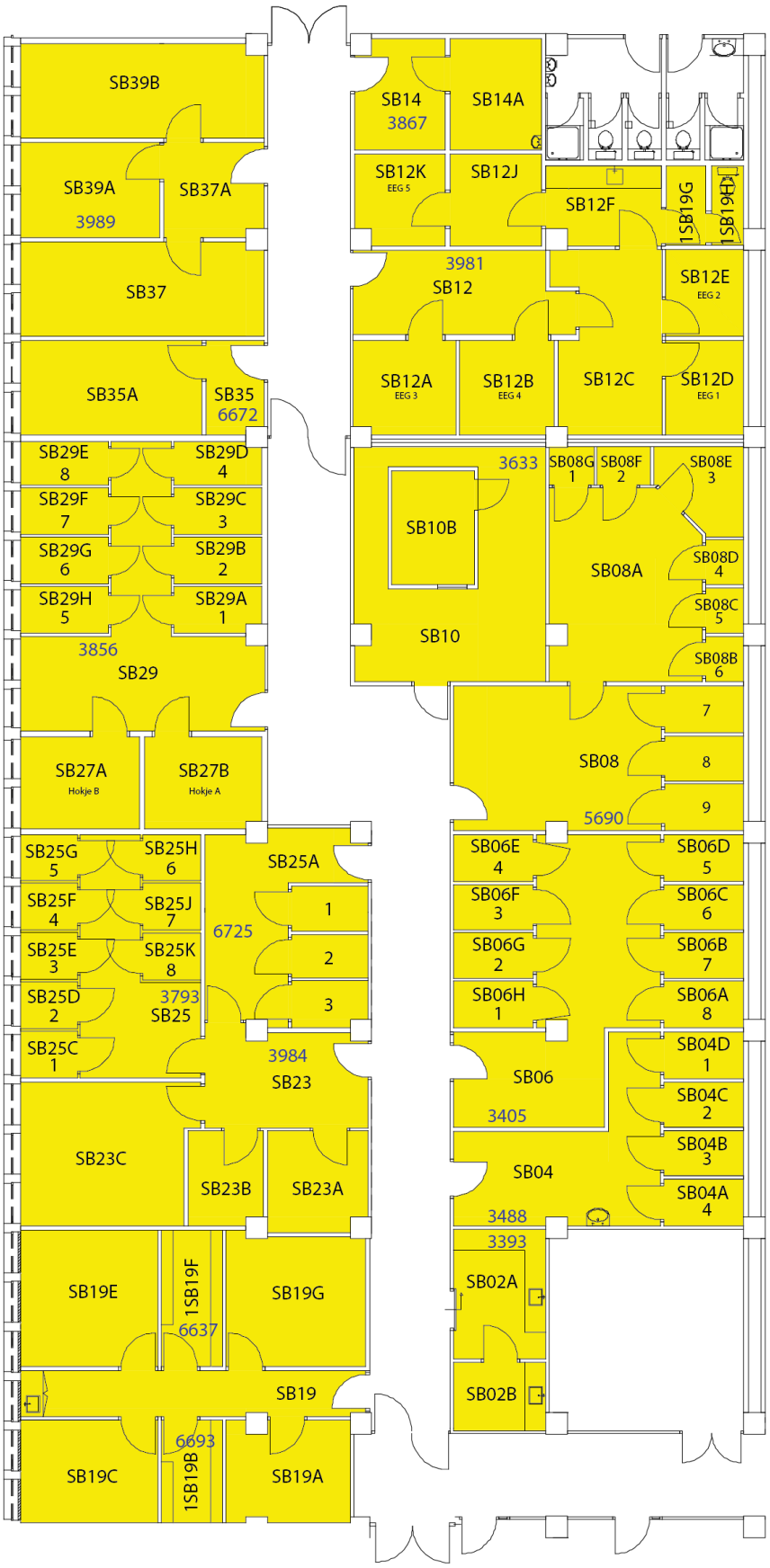
In the Pieter de la Court building (PdlC) a large number of research and observation rooms are available for scientific research. These are located on the first floor and in the basement.

Lab	Type of research	Comments	supervisor
SB04	Physiology	4 cubicles, water	S&O
SB06	e-prime behavioural research and authorware	8 cubicles	S&O
SB08	e-prime behavioural research, presentation, psychopy	9 cubicles	COG
SB10	Sound-critical research	sound-proof cabin	COG
SB12	EEG	5 labs, kitchen, toilet	COG, S&O, KP, O&O
SB14	EEG	1 cubicle for 2 people, water	KP
SB19	Physiology, sensory stimuli, observation	4 rooms and 2 observation booths, water	GMN
SB23	observation, physiology	2 rooms and 1 observation booth	S&O
SB25A	e-prime behavioural research, presentation, psychopy	3 cubicles	COG
SB25	e-prime behavioural research and authorware	8 cubicles	S&O
SB27	EEG research	Faraday cage in SB27B	COG
SB29	e-prime behavioural research, presentations, psychopy	10 cubicles	COG
SB35	EEG, physiology, sensory stimuli	1 space, water	GMN
SB37	Physiology, EEG, eye tracking and observation	combination with SB39, water, 2 rooms and 1 observation booth	O&O
SB39	Physiology, EEG, eye tracking and observation	combination with SB37, water, 2 rooms and 1 observation booth	O&O

Table 1: Basement

Lab	Type of research	Comments	supervisor
1.B18	virtual identity	water	COG
1.B18A	observation		COG
1.B23	eye tracking		SOLO
1.B24	eye tracking, NIRS, observation	water, baby lab	AGP
1.B24A	observation		AGP
1.B25	Physiology	water	KP
1.B25A	e-prime behavioural research		KP
1.B27	Physiology, sensory stimuli		KP
1.B27A	observation		KP
1.B28	Physiology, eye tracking and observation	water, baby lab	ORT
1.B28A	observation		ORT
1.B30	e-prime behavioural research, presentations, psychopy	water	COG
1.B31	e-prime behavioural research		KP
1.B33	eye tracking		KP
1.B33A	e-prime behavioural research		KP
1.B34	Physiology	water	GMN
1.B34A	observation		GMN
1.B35	Physiology		KP
1.B35A	e-prime behavioural research		KP
1.B37	eye tracking		KP
1.B37A	observation		KP
1.B39	general	1 space	SOLO
1.B40	general	water	SOLO
1.B40A	observation		SOLO
1.B41	observation		AGP
1.B41A	observation		AGP
1.B43	EEG	water, indoors	AGP
1.B43A	observation		AGP
1.B44A	general	water, 1 space	SOLO
1.B45	Physiology, observation		AGP
1.B45A	observation		AGP
1.B47	Physiology, observation		AGP
1.B47A	observation		AGP
1.B50	robotics		COG
1.B56	Meditation research	Separate meditation room	COG

Table 2: First floor


SB39B
SB39A
3989
SB37A
SB37
SB35A
SB35
6672
SB29E
8
SB29D
4
SB29F
7
SB29C
3
SB29G
6
SB29B
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SB29H
5
SB29A
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3856
SB29
SB27A
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SB25E
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SB25D
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3793
SB25
SB25C
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SB25A
6725
1
2
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3984
SB23
SB23C
SB23B
SB23A
SB19E
1SB19F
6637
SB19G
SB19
SB19C
6693
1SB19B
SB19A
SB14
3867
SB14A
SB12K
EEG 5
SB12J
SB12F
1SB19G
1SB19H
3981
SB12
SB12E
EEG 2
SB12A
EEG 3
SB12B
EEG 4
SB12C
SB12D
EEG 1
3633
SB10B
SB10
SB08G
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SB08F
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SB08E
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SB08C
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SB08B
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SB08
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SB06E
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SB06D
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SB06F
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SB06C
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SB06G
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SB06B
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SB06H
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SB06A
8
SB06
SB04D
1
3405
SB04C
2
SB04
SB04B
3
3488
SB04A
4
3393
SB02A
SB02B

Laboratories PdlC First floor

Roles and responsibilities

Ethics committee: research that falls under the Medical research involving people Act (*Wet medischwetenschappelijk onderzoek met mensen,* WMO), must be approved by an independent committee of experts. Without a positive assessment from this committee the research project cannot start. Within Leiden University we have three separate committees:

- METC – Medical Ethics Assessment Committee (*Medisch Ethische Toetsingscommissie*)
- Ethics Commission (Child and Family Studies) (*Commissie Ethiek, Pedagogiek)*
- CEP – Ethics Commission Psychology (*Commissie Ethiek Psychologie*)

Science Policy Committee: advisory body consisting of representatives of the Faculty Board, the faculty office, the lab coordinators and the scientific directors of the institutes. The Science Policy Committee is responsible for policy as far as it pertains to beta-medical research and distribution of funding.

Lab coordinator: the lab coordinators are responsible for the day to day running of the laboratories and are the first port of call for researchers who want to use the labs for their studies. The lab coordinators manage the diaries and the lab keys, and ensure that the labs are clean and tidy.

Scientific director: the leader of an institute's scientific direction and research.

Faculty Board: The Faculty Board is the highest executive body in the faculty and is supported by the faculty office.

Duties of the Faculty Board:

- To determine the course programmes, with prior agreement from the Faculty Council, and to provide more detailed regulations for the scope and content of the examinations;
- To formulate the faculty regulations, with prior agreement from the Faculty Council;
- To approve the research programmes;
- To establish the annual budget for the faculty;
- To advise the Executive Board on the appointment of professors.

Responsibilities

The Faculty Board is accountable to the Executive Board. The Faculty Board is responsible for:

- The organisation and coordination of teaching and research in the fields covered by the faculty;
- The oversight of the implementation of teaching and research programmes;
- The meetings with the Faculty Council, and subsequently the dissemination and implementation of the decisions made at these meetings.

SOLO: The *SOLO* department *(Support for Research, Laboratories and Education/Support voor Onderzoek, Laboratoria en Onderwijs)* offers support to teachers and researchers at the FSW who are working in education, research and laboratories. In addition to this, the department is responsible for information management.

Research and lab support facilitates research within the faculty's science laboratories and scientific studies on location. Before the start of a research project, researchers can come to the department for advice about setting up the project, what measurement equipment to use, and the optimal settings. The research technicians also programme E-Prime tasks and MATLAB scripts for the processing and analysis of the physiological and eye track data that have been collected. The lab technicians will liaise with the lab coordinators about any changes to be made to the labs in order to make them suitable for the new study and solve any urgent problems in the labs. In addition to this, the lab technicians are responsible for ordering measurement equipment, leads, and lab disposables. Any studies done with the fMRI scanner are also officially supported by the department for one day a week.

Location management: The department advises the Faculty Board on the (safe) use, allocation and layout of the rooms and oversees the implementation. In addition to this, it provides a number of support services that fall under the FSW Service desk. The location manager acts as a demand manager for the UFB (*Universitair Facilitair bedrijf*, General Services Department) and as lab coordinator.

Space requirements and allocations

The total space available for scientific research in the PdlC building is limited. To make the best possible use of this space, a number of ground rules have been agreed about the allocation:

- Lab facilities are the property of the Faculty of Social and Behavioural Sciences, Leiden University, which has allocated them to the Institutes of Psychology and Child and Family Studies for the purpose of carrying out their studies; they are managed by the lab coordinators;
- The lab coordinators receive and deal with any and all requests to use the existing lab facilities;
- First, the availability and suitability of the existing lab facilities will be determined. After that, lab spaces that are in use by other institutes can be assessed. Should the existing lab spaces be suitable but in need of alterations, SOLO can be approached for this.

NB. Any necessary equipment will not immediately be purchased following a (first) application. The decision to purchase equipment is dependent in part on the location of the research project. In some cases it is possible to use equipment that is already available. This ensures that it is not necessary for the faculty or researchers themselves to buy equipment for every research project.

General safety of staff and participants

Within the Faculty of Social and Behavioural Sciences, studies involve participants of all ages. The Faculty is responsible for the safety of these participants, but also for that of the staff. In order to guarantee and ensure their safety, a number of basic protocols and guidelines have been drawn up that everyone involved in research with human participants must adhere to.

The ground rules that must be followed are:

- The four eyes principle
- Criminal records check (VOG, *Verklaring omtrent het gedrag*))
- Personal hygiene
- Demonstrable competence with regard tothe use of equipment
- Demonstrable competence with regard toworking with blood and other body tissues and cells
- Demonstrable competence with regard toworking with pharmacological manipulations

The Calamity Protocol, which has been drawn up in case of a calamity, also applies.

NB. Access doors to the laboratories will not be locked if someone is inside.

Quick link to:

Laboratory set up

Each lab should be neat, tidy, and organised. This also means that there must not be any trailing or dangling wires. There should also be information in the space about the lab in question, and appropriate safety instructions.

There are many different types of rooms for scientific research. Each of these rooms is set up in its own specific way, determined by the intended use and safety considerations.

- Room for conducting studies:
  - Equipment-based research;
  - Observations;
  - Computer-based tasks.
- Room for collecting body tissues and cells and temporary storage
- Room for storage of body tissues and cells (temporary and long term)

NB: Please be sure to use of the sliding sign on the door! That way it is instantly clear whether someone is using the room.

Quick link to:

Guidelines on the setup of science facilities
Storage of body tissues and cells
Research equipment
Furniture

Support for science facilities and research equipment

Research and lab support at the PdlC building is aimed at the studies carried out in the faculty's beta-medical laboratories, as well as beta-medical research on location (this also includes mobile equipment such as heart rate monitors and GPS trackers). Before the start of their study, researchers can come to the department for advice about setting up the project, what measurement equipment and online platforms (e.g. Qualtrics) to use, the optimal settings, and data management. The department has also recorded How To-videos explaining the working of a specific piece of equipment. In addition to this, the research technicians programme E-Prime tasks and MATLAB scripts for the processing and analysis of the physiological and eye track data that were measured. The lab technicians will liaise with the lab coordinators about any changes to be made to the labs to make them suitable for the new study, and will solve any urgent problems in the labs. Any research done with the fMRI scanner is also officially supported by the department for one day per week. The lab technicians are responsible for ordering measurement equipment, leads, and lab disposables.

Quick link to:

Science Support Protocol

Definitions

Participant: A person who takes part in a study

Research leader: The person who is undertaking a scientific study

Lab: a space in which a scientific study is carried out on participants

Scientific study: a rigorous, verifiable, and systematic study of a particular matter according to conventions as established by the scientific community. The purpose can be to discover or establish certain facts or principles, and/or the application of knowledge for practical purposes.

Equipment: devices and peripherals used in the study that is carried out with the participants.

Observations: Conscious, focused, and accurate observations of a participant, to determine his or her symptoms and/or behaviour and the reactions to a treatment and experimental manipulations.

Researcher: someone who is conducting a scientific study. A practitioner of science/an academic.

Section chair: leader of a section within the institute.

Body tissues and cells: any elements separated from the human body and foetal matter, such as hair, oral mucus, bone marrow, or an organ.

Protocol: a code of behaviour, usually in the form of a number of steps to be followed. There are various types of protocols, such as communication protocols, computer protocols, scientific protocols, ceremonial protocols, ethical protocols, and treaty protocols.

Policy: sets out coherent aims, resources, and a time frame. It is best if place and time are specified. A policy is therefore the means by which an organisation sets a course and determines the resources with which it intends to achieve its stated aims within the established time frame.

Guideline: guidance on how something should be done and what is not permitted

Data management (digital data)

To be written up

Insurance for participants

Leiden University and the LUMC have taken out insurance with respect to possible harm that could come to a participant as a result of taking part in this study. This pertains to harm through death or injury that manifests during participation in the study, and harm that manifests within four years of participating in the study.

The insured sum is:
1) € 650,000
For harm **per participant**,
2) € 5,000,000
For harm to all participants involved in **this study** together and
3) € 7,500,000
For the total harm caused per insurance year to participants across **all studies** undertaken by or on behalf of the client per insurance year.

This insurance cover does NOT include:

- Harm that is the result of the participant's health issues not improving or getting worse, where participation in the study is part of the treatment of these health issues;
- Harm through damage to the participant's health that is likely to have manifested itself even if the participant had not taken part in the study.
- Harm through damage to the participant's health where this harm is the result of participation in a scientific study that consists of comparing two or more common treatments or procedures;
- Harm that manifests itself in descendants as a result of negative impact from the study on the participant and/or their descendant;
- Harm that is certain or almost certain to befall the participant because of the nature of the study;
- Harm that is the result of not or only partially following guidance and instructions on the part of the participant, as far as the participant is able to do this;
- Harm that is the result of a risk occurring that you have been warned of in the written information, unless the risk is more serious than anticipated or if the risk was highly unlikely.

The insurance company responsible for the policy:

Onderlinge Waarborgmaatschappij Centramed B.A.
Appelgaarde 4
2272 TK Voorburg

CentraMed
Zorgvuldig

WMO-VERKLARING

polisnummer 624.530.305

TEN BEHOEVE VAN
DE COMMISSIE VOOR MEDISCH-WETENSCHAPPELIJK ONDERZOEK
EN WIE HET VERDER MOGE AANGAAN.

Leids Universitair Medisch Centrum en/of Academisch Ziekenhuis Leiden en/of Universiteit Leiden Faculteit der Sociale Wetenschappen, Faculteit der Geneeskunde en Faculteit Geesteswetenschappen, alle inclusief subfaculteiten, hierna te noemen de instelling, heeft bij de onder D vermelde verzekeraar en ondertekenaar van deze verklaring, ten behoeve van proefpersonen, een doorlopende verzekering afgesloten, voor medisch-wetenschappelijk onderzoek dat aanvangt in de periode 1 januari 2018 tot 1 januari 2019.
De verzekering voldoet aan de gestelde eisen in de Wet medisch-wetenschappelijk onderzoek met mensen en het Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015.

A. Verzekerde bedragen

A1	€ 650.000,=	als maximum per aanspraak per proefpersoon, met een maximum van
A2	€ 5.000.000,=	per afzonderlijk medisch-wetenschappelijk onderzoek, met dien verstande dat indien de instelling meerdere wetenschappelijke onderzoeken verricht of heeft verricht het totale verzekerde bedrag is gelimiteerd tot
A3	€ 7.500.000,=	voor schade die zich per verzekeringsjaar door medisch-wetenschappelijk onderzoek openbaart.

B. Uitsluitingen ten aanzien van de proefpersonen

De verzekering dekt niet:

B1 Aanspraken voor schade die zich openbaart bij nakomelingen als gevolg van een nadelige inwerking van medisch-wetenschappelijk onderzoek op de proefpersoon en/of de nakomeling.

B2 Aanspraken voor schade waarvan het op grond van de aard van het medisch-wetenschappelijk onderzoek zeker of nagenoeg zeker is dat deze zich zou voordoen.

B3 Aanspraken voor schade die het gevolg is van het niet of niet volledig opvolgen van aanwijzingen en instructies door de proefpersoon, voor zover de proefpersoon daartoe in staat is.

C. De polisvoorwaarden Proefpersonenverzekering Centramed 2015 prevaleren en kunt u te allen tijde bij ons opvragen.

D. Onderlinge Waarborgmaatschappij Centramed B.A.
Postbus 7374
2701 AJ Zoetermeer

Zoetermeer, januari 2018

M.G. Bakker

www.centramed.nl

3180 0000

Onderlinge Waarborgmaatschappij Centramed B.A., Maria Montessorilaan 9, 2719 DB Zoetermeer, Postbus 7374, 2701 AJ Zoetermeer • T (079) 301 79 79 • info@centramed.nl • Bank: NL83 INGB 0680 3235 46 • BIC: INGBNL2A • KvK Haaglanden: 08063107

Signatures

Thus determined and agreed.

……. *(signature)*	……. *(signature)*
……. *(date)*	……. *(date)*
Member, Faculty Board	*Member, Science Policy Committee*

Appendices

Calamities Protocol

Medical emergencies (for example, the person is unresponsive, having convulsions, a heart attack or less serious symptoms such as nausea, dizziness, (near) fainting):

- Ensure that the person is safe (disconnect any equipment, sit or lay the participant down on the floor so that they cannot hurt themselves)
- Call reception: (071) 527 3701. This number can also be found on the lab signs on the inside and outside of all doors leading from a lab into the corridor. Reception will call for the appropriate type of assistance, for example from the First Aid/Emergency Response Officer (BHV).
- Briefly describe the situation
- Give your location: floor, room number, specific location if there are several smaller rooms within the space.
- State whether the door to the corridor is open or locked
- Ensure that the space is accessible: get someone to open the door and ask this person to wait for the emergency services at the entrance [to the space], so that they can be taken directly to the right place;
- In all situations: STAY WITH THE PARTICIPANT YOURSELF!
- Then call someone from the research team (preferably the supervisor), and then the lab coordinator.
- Normally, the First Aider / Emergency Response Officer will only leave when the person has recovered, or is recovering but is out of danger past. Should the participant's condition deteriorate, please phone (071) 527 3701 again.
  If the participant does recover: the First Aider / Emergency Response Officer will brief you on the procedures to follow after an incident. This will roughly involve the following, but do follow any instructions from your First Aider / Emergency Response Officer carefully.
- Ask the patient what they think caused the incident (without suggesting causes yourself).
- Ask the patient if they are happy to leave by themselves or whether they can call someone to accompany them home. In all events, walk with them to the exit, to observe whether they have definitely recovered.
- Phone the participant the next day at the latest to ask how they are doing; if necessary, phone back until they have completely recovered. Do warn the participant that you will call. If symptoms persist or if the participant is at all worried, advise them to contact their GP.

Fire / Explosion:

- Call reception and report the situation: (071) 527 3701
- Clear the lab: disconnect the participant from any equipment as quickly as possible and leave via the nearest (emergency) exit. Do not use the lift.
- In the event of an acute fire incident, set off the fire alarm by breaking the glass in the hallway; various people will respond immediately and the fire brigade will be automatically notified.
- Electrical current passing through someone's body: Press the red button in the study leader's space, if present. Then follow procedure for medical emergencies.

Evacuation signal building (slow-whoop):

- Evacuate the lab: disconnect the participant as quickly as possible and leave together via the nearest (emergency) exit.

Aggression/intimidation:

- Call for help ASAP. This should in the first instance be a receptionist: (071) 527 3701. If you are expecting problems: ensure you are not alone in the lab and always apply the four eyes principle.

Four-eyes principle Protocol

In the case of studies involving participants, the FSW employs the four eyes principle. The purpose of the four-eyes principle is to avoid situations that can provide an opportunity for intimidation, (sexual) assault or abuse while a study is being carried out within the FSW. It also creates a culture of accountability within the FSW between the participants and the staff (lab coordinator, research leader, staff and students). The four eyes principle creates a safe environment within the FSW research facilities for both FSW staff and students, and the participants.

In practice, this means that all studies conducted on participants are organised in such a way that the FSW staff member or student may conduct the study with the participant only if they can be seen by another staff member or student of the FSW. No one may conduct a study with participants on their own.

The second staff member or student can intervene or call for help ((071) 527 3701) he/she feels that a boundary has been crossed.

Requirements of the four eyes principle:

- Research with participants may only be carried out if the person carrying out the study can be seen by another member of FSW staff or a student
- Minors are not eligible for employment intended to comply with the four-eyes principle (bear this in mind when it comes to students);
- The second staff member or student may be in the same room as the participant and the researcher, but may also be in an adjacent observation room which has a window into the research space;
- Camera supervision is also permissible, as long as the camera image is constantly watched and the space where the screen is located is near the research space to allow for rapid intervention;
- In the case of a study involving minors, the parent can also act as the second adult present, as long as the safety of the staff member or student who is carrying out the study cannot be compromised, and as long as the presence of the parent does not affect the study;
- If the lab coordinator, research leader, FSW staff members, or students become aware of studies being carried out in which the four eyes principle is not being applied, they can report this to the Academic Director of the institute in question.

Policy on Criminal Records Checks (VOG)

It is FSW policy that all faculty employees carrying out studies with participants who are under 18 must have a recent (issued within the last 3 years) Criminal Records Check (VOG) and be able to produce it when asked. It is up to the individual institutes to ensure that their administration on this point is in order. They are also responsible for the cost of obtaining a Criminal Records Check from the Ministry of Justice and Security. (*Ministerie van Justitie en Veiligheid)*

If students are performing studies on participants who are under 18, they must be supervised (read: accompanied) at all times by a researcher who is employed at the faculty and has a Criminal Records Check.

Criminal Records Checks can be requested on this website: www.vog-aanvraag.nl

NB. A general policy for Leiden University relating to Criminal Records Checks is currently being drawn up. After completion this can be integrated with FSW policy.

Informed Consent Form Protocol

Participants in a study involving the FSW must give their prior written consent. In order to come to an informed decision, they must be given enough time between being informed and being asked for consent. How much time is deemed reasonable to come to this decision will depend on the type of study.

The informed consent form must adhere to stringent requirements. Within the FSW we use the informed consent form provided by the Central Committee on Research involving Human Subjects (CCMO, *Centrale Commissie Mens Gebonden Onderzoek*). The form must state to which study it applies, and what the consent is required for within the study. Only after the informed consent form has been signed by the participant and they have been given a copy of the signed form can the project start. Sometimes the researcher may wish to inform the participant's GP or consultant that they are taking part in the study. This must be stated in the informed consent form, and the participant must give permission.

If tissues or cells are collected for the study and they need to be stored long term, this must also be stated in the informed consent form. If the body tissues or cells collected are to be used in the future a different study to the one the participant has signed for, the participant must be asked for his/her consent again. Future use of body tissues and cells may already be included in the informed consent form for the study that the participant was originally asked to take part in.

Who can sign the informed consent form?

- Adult participants who are of sound mind (aged 16 years and over) may sign the informed consent form themselves
- Children and young people under the age of 16 need consent from their legal representative. Young people aged 12 and over will need to sign the informed consent form themselves as well.
- Adult participants who are not of sound mind (aged 16 years and over) need consent from a legal representative

The informed consent form can be found on the CCMO website: http://www.ccmo.nl/en/consent

Protocols on the Safe Use of Science Facilities

General Rules on Hygiene for Researchers

Aim

To ensure good personal hygiene on the part of the researcher, which will protect him/her and the participant against infections.

Nails

- Nails must be kept short and clean;
- Dirt under the nails must be brushed away carefully, with a soft brush;
- Nail polish, acrylic nails or other forms of false nails are not permitted.

Hair

- Hair must be clean;
- Long hair must be worn up or pulled back.

Facial hair

- Beard and moustache must be clean and properly cared for.

Jewellery

- During research, no rings, bracelets, piercings or watches may be worn on hands or underarms, as it makes it impossible to properly clean the skin in these areas.

Piercings

Piercings are not permitted if they:

- interfere with the treatment/care of the participant;
- make it impossible for general hygiene practices to be carried out or carried out properly;
- are a possible source of infection for the participant.

Cough, sneeze and toilet hygiene

- Turn away when you cough / sneeze;
- Cough / sneeze into a handkerchief / tissue or into the crook of your elbow;
- Use a tissue when blowing your nose;
- Only use a tissue once and immediately throw it in the bin after use;
- Wash your hands after coughing, sneezing, blowing your nose or visiting the toilet.

Eating and drinking

Do not eat or drink in areas where work is carried out with human test subjects, or on participants' tissues or cells.

Clothing

In venepuncture:

- Wear buttoned or zipped up, clean clothing with short sleeves (tip: own lab coat);
- Bandage up any injuries and wear disposable gloves (latex free);
- Do not wear any rings, watches or bracelets (including under the gloves);
- do not wear clothing and/or accessories that can sweep around the working area (bear this in mind when wearing items such as cardigans, scarves, headscarves or necklaces);

Footwear

Shoes must be easy to clean and footwear must be cleaned whenever there is visible dirt.

Plaster cast or hand/wrist braces

Plaster casts and hand or wrist braces are not permitted, as they prevent the researcher from carrying out proper hand hygiene procedures.

Hand hygiene Protocol

Aim

To prevent the transfer of micro-organisms via the hands by applying proper hand hygiene.

Abbreviations and definitions

- **Hand hygiene:** washing, disinfecting, and caring for the hands;
- **Hand washing:** removing dirt and part of the transient (various temporarily present micro-organisms) flora on the hands. The hands are washed with water and liquid hand wash and dried with a disposable towel;
- **Disinfection:** the killing and reducing of transient and resident (micro-organisms that are always present on the skin) flora on the hands. The hands are rubbed with hand alcohol until the hands are dry.
- **Hand care:** moisturising the hands after disinfecting

General remarks

- Hands play an important part in the transfer of micro-organisms. Good hand hygiene is the most important method for preventing this from happening;
- In order to make good hand hygiene possible, rings, piercings, watches and bracelets are not permitted;
- Nails must be kept short and clean. Dirt under the nails must be brushed away carefully, with a soft brush;
- Nail polish, acrylic nails or other forms of false nails are not permitted;
- Do not disinfect hands after washing hands. Double hand hygiene is unnecessary, inefficient, and puts too much stress on the skin;
- Carry out hand hygiene before putting on gloves and directly after taking them off.

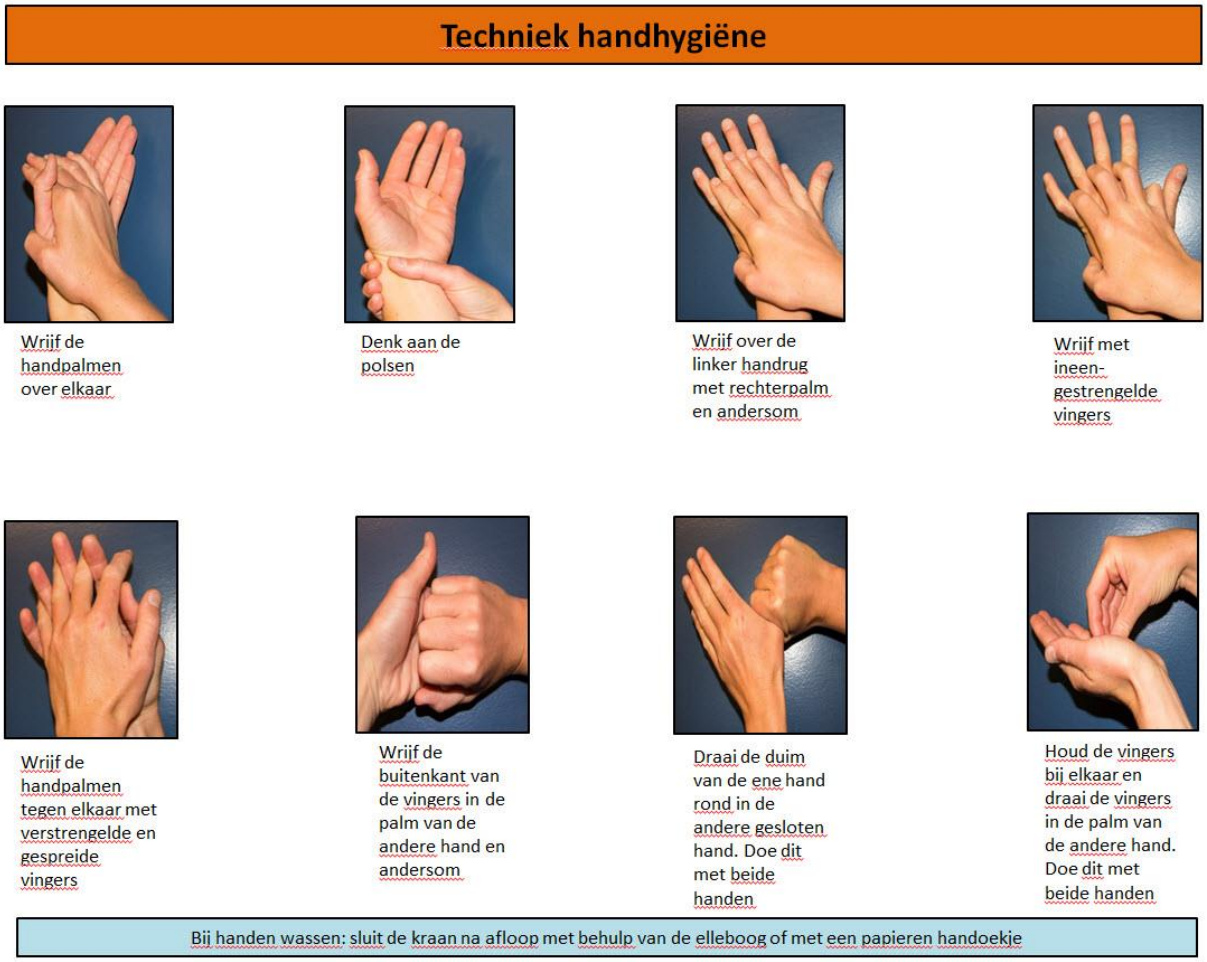
When to wash hands

- Always before the start of research activity;
- In the case of visible or noticeable contamination;
- After visiting the toilet;
- After sneezing, coughing and blowing one's nose;

When to disinfect hands

- Before touching the participant;
- Before and after collecting organic matter.
- After touching the participant (to prevent the participant's pathogens (micro-organisms that cause disease) from spreading further via the researcher).

NB1: Hands must be disinfected before contact with the participant. After contact, hands must be disinfected again. Should there be another participant straight afterwards, it is not necessary to disinfect hands again before contact is made, provided there has not been any contact with the environment in-between.
NB2: Hand alcohol is preferable to using soap and water. Hand alcohol has a greater germ-reducing effect, is more skin friendly (because of the added moisturising ingredient) and can be applied more quickly.



[Translation of text in image:

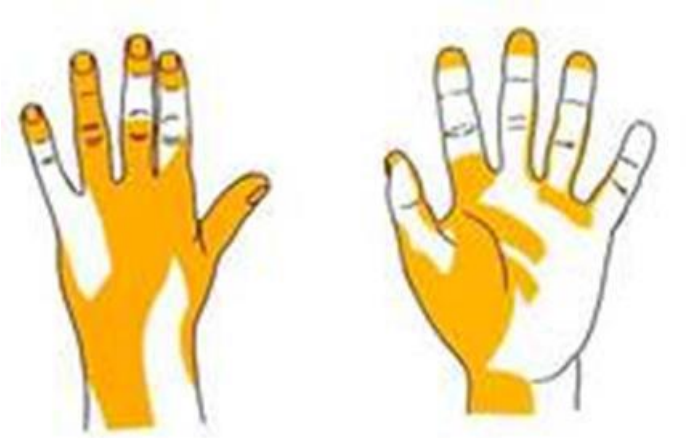
Hand hygiene technique
Rub palms together
Remember the wrists
Rub the back of the left hand with the right palm and vice versa
Rub between the fingers
Rub palms together with laced, spread fingers
Rub the outside of the fingers on the palm of the other hand and vice versa
Grab the thumb of the other hand and twist. Repeat for the other thumb.
Rub the fingertips in the palm of the other hand. Repeat for the other hand.
After washing hands, close the tap using your elbow or a paper towel.]

Disinfecting your hands

- Fill the hollow of your dry hands with hand alcohol from the dispenser. Take as much as is needed to cover all of your hands and wrists;
- Follow the technique described above. This procedure will take around 30 seconds;
- If the hand alcohol has not dried up (enough), effectiveness is reduced and skin irritation may occur.

Hand washing

- Open the tap and let the water run;
- Wet your hands thoroughly. Get some soap out of the dispenser;
- Follow the technique described in the pictures above;
- Rinse your hands thoroughly;
- Turn the tap off with a paper towel;
- Dry your hands and wrists thoroughly with a clean paper towel;
- Throw the used towel in the bin.



The above image shows the parts of the hands that are most usually skipped: the fingertips, the areas between the fingers, and the thumb.

Venepuncture Protocol

Aim

Every researcher who will be taking blood from participants must be adequately trained to take blood independently, so as to ensure the safety not only of the participant but also that of the member of staff.

Training on taking blood (venepuncture) for new staff members

Before researchers can independently collect blood samples, they must be able to show proof of competence in the form of the "Checklist for assessment of practical skills: venepuncture". If they do not have this, they must complete a training course.

Preparation

Make sure all the necessary equipment for taking blood samples is to hand (see Supplies).

Equipment:

- Tourniquet
- Sterile specimen bottles
- Disposable gloves
- Safety needle Eclipse (BD)
    - Eclipse 22G
    - Eclipse 21G
- Butterfly needles (push button butterfly needle, BD)
    - Push Button 23G
    - Push Button 21G
- Cutisoft gauze
- Leukopor tape
- Disinfectant (Chlorhexidine solution 0.5% or alcohol 70%)
- Waste disposal container: Sharps bin and clinical waste container

Procedure

While collecting blood samples, make sure that:

- The safety of the participant and the researcher is ensured;
- The quantity of blood taken is kept to a minimum;
- The risk of complications as a result of the venepuncture is kept to an absolute minimum;
- The venepuncture takes place in the appropriate place within the FSW science labs, and the participant is sitting in the prescribed chair. It is forbidden to collect blood in any other location, i.e. , the science labs, canteens, showers or toilets;
- In the faculty building only safe needles may be used.

General hygiene

- See the "General hygiene" protocol

Cleaning and disinfecting hands

- Please see the protocol on "Hand hygiene" for the proper hand hygiene procedure
- When starting work (at the start of the day or after a break), you must always wash your hands.
- Hands must also be cleaned before and after contact with each participant by washing or disinfecting.
- Hands must also be cleaned:

    - In case of visible or noticeable contamination.
    - After contact with bodily fluids and mucous membranes.
    - After visiting the toilet.
    - After sneezing, coughing or blowing your nose.
- You should also disinfect your hands in the following situations:
    - Before contact with invasive devices, even if gloves are to be worn.
- After use of disinfectants, allow the skin to air dry completely.
- After disinfecting a participant's skin, you must not touch the cleansed area again with your hands.

Tourniquet

A tourniquet applies greater pressure to the vein, making it easier to feel and see.

- Apply the tourniquet one hand-width above the site of collection and tighten it, keeping one or two fingers between the fastening of the tourniquet and the arm;
- It is easy to find veins by hand. They feel springy which makes them easy to distinguish from muscles and tendons;
- Keeping the tourniquet on for too long will reduce the quality of the sample, so do not compress for longer than 1 minute;
- If the tourniquet is in place for longer, there will be measurable differences in the concentration of various blood components. If you have been compressing for longer, you should release the tourniquet for a moment before collecting blood;
- It is best not to ask the participant to make a fist. Creating this extra compression increases the chance of higher potassium and haemolysis;
- The (non-disposable) tourniquets are cleaned afterwards with Incidin. The researchers are responsible for this.

Procedure for venepuncture

- Wash and/or disinfect your hands according to the protocol;
- Tell the participant what you will be doing and ask if he/she has a preference for a particular arm. Respect the participant's choice in this;
- Check that the bottles have been labelled with the correct identifying information as per the research protocol. Verify the identification by asking for name and date of birth and checking this against the order label;
- Get the necessary equipment ready (see Equipment);
- Choose a site (see Choosing a collection site);
- Ask the participant to hyperextend his/her arm;
- Disinfect the collection site with chlorhexidine solution 0.5 % (skin disinfectant);
- After using the disinfectant, allow the skin to air dry completely;
- After disinfecting, you must not touch the cleaned area with your hands again;
- Palpate for the vein and check that the vein you have found is not pulsating (you could have found an artery);
- If the arm that was offered (the preferred arm) is not suitable, you should try the other arm. If no venepuncture can be performed on that arm either, then venepuncture cannot take place;
- Apply the tourniquet a hand's width above the collection point, but do not pull it too tight (< 1 minute);
- Pull the skin taut and insert the needle, with the opening facing upwards, at an angle of about 15-35 degrees;

- Connect the collection bottles in the correct order and release the tourniquet;
- Fill the bottles completely;
- Invert the bottles a number of times immediately;
- Press a piece of gauze against the site when enough blood has been drawn and then calmly pull the needle out of the vein;
- With the thumb of the hand that is holding the needle, press the safety cap over the tip of the needle until you hear a click;
- Firmly press the vein shut or ask the participant to apply pressure themselves. Never ask them to bend their arm, as this can cause a haematoma;
- Immediately dispose of the needle in the sharps container;
- Once the bleeding has stopped, tape off the collection site (if bleeding continues for longer, you should get the participant to continue to press down while you apply a compression bandage);
- If the bleeding has not stopped after 10 minutes, call Reception on (071) 527 3701.

NB: tubes must be cleaned and disinfected before being stored.

Complications

In case of suspected heart failure: call (071) 527 3701. See Calamities Protocol

Fainting during blood collection

Always be aware that this can happen. Early warning signs are feeling dizzy, nausea, sweating, muffled hearing and yawning.

- Tilt the chair backwards (if possible) so that the participant is lying down;
- Warn Reception (071) 527 3701!
- Stay with the participant;
- Give them space and loosen any tight clothing.

Blood is no longer flowing into the tube

- Press the tube firmly into the rubber top. If the blood is now flowing into the tube again, it means the lid was not properly punctured;
- Pull the skin taut or tilt the needle a little. If the blood is now flowing into the tube again, it means the needle was sticking to the inside of the vein;
- Pull the needle back a little. If the blood is now flowing into the tube again, it means the tip of the needle penetrated the other wall of the vein (watch for haematoma);
- Push the needle in a little further. If the blood is now flowing into the tube again, it means that the needle was not properly inside the vein;
- Use a new tube. If the blood flows into the new tube, it means there was no vacuum in the tube;
- If the tube is not filled completely, vent the tube by lifting the lid or vent the tube by puncturing (aerating) the tubes in the right order with a new needle;
- If these actions do not resolve the problem, end the blood collection and find another site;
- You may only make a second attempt if you are confident that this attempt will be successful. If not, consult a colleague.

Pain during blood collection

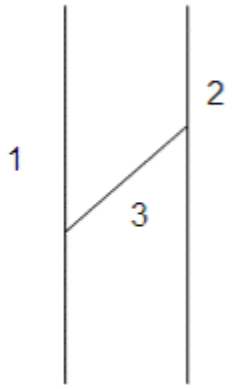
This may be caused by puncturing a nerve, tendon or artery. Stop the blood collection. In the case of a perforated artery, firm pressure must be applied to the collection site and the Calamities Protocol must be followed.

Haematoma

This may occur if the needle has been pushed through the vein. Apply pressure to the collection site and reassure the patient.

Venepuncture site selection

There are various superficial veins in the arm that can be used for collecting blood. Two anatomic patterns can be discerned in the veins in the arm: the H-shape.



1. Cephalic Vein 2. Basilic Vein 3. Median Cubital Vein

 The order of preference for the collection site is:

- Median Cubital Vein.
- Cephalic Vein.
- Basilic Vein.

Checklist: Assessment of practical skills for venepuncture

Name: Date: Date of birth:

The numbered steps must be completed in the order given.

Method Venepuncture	Assessment			
	yes	no	Right	wrong
Staff member is not wearing any jewellery on hands				
Supplies.				
- Puts out gauze				
- Puts out tourniquet				
- Puts out tape				
- Evacuates tubes and puts them out				
- Puts out needle				
- Has sharps container ready				
Procedure				
Asks for date of birth and name, checks these against the dosage schedule (positive identification)				
1 Takes needle out of the packaging				
2 Chooses a site that causes the least amount of inconvenience for the patient.				
3 Applies tourniquet				
4 Locates the vein and identifies collection site.				
5 Punctures vein				
6 Attaches the blood collection tube to the needle				
7 Releases tourniquet during blood withdrawal				
8 Removes the tube and the needle				
9 Inverts the tube 3x				
10 Applies pressure to the collection site with gauze and asks the participant to press down firmly.				
11 Disposes of needle in the sharps container.				
12 Tapes down gauze with tape				
13 Removes tourniquet				
14 Checks for bleeding				
15 Affixes barcode sticker to the tube or records name, date of birth and Outpatient clinic / destination on the tube.				
Complications				
- Checks for continued bleeding by checking if there is blood coming through the gauze				
- Replaces gauze if necessary				
- Member of staff knows what to do in case of a needle stick injury (yellow card)				
Has the execution of the entire procedure been judged satisfactory?				

The execution of the entire procedure is satisfactory if the steps to be carried out have all be assessed with Yes and Good.

Name of assessor:

Assessor's signature:

Needle stick injuries Protocol

Topic
What to do if you are the victim of a needle stick injury.

Applies to
FSW researchers

Definitions / abbreviations
Needle stick injury: any event in which the participant's blood can come in contact with the blood or saliva of persons working for Leiden University; this means that in addition to the puncture of the skin, bites, cuts or blood spatters in the eye also fall under needle stick injuries. Any incidents involving laboratory materials should also be dealt with according to this protocol.
The source patient: the participant whose blood is involved.
The exposed person: the FSW researcher who has come into contact with the source patient's blood during the course of their work through a needle stick injury.
VGM: Safety, Health and Environment

Procedure
General remarks
- Avoid needle stick injuries by working hygienically and safely.
- Report any needle stick injuries and any contamination with blood and/or other bodily fluids with the VGM department on (071) 526 3643 (needle stick injuries) or by email at secretariaat_vgm@lumc.nl.
- You can visit the VGM department for a Hepatitis-B vaccination without an appointment, Monday to Friday between 8.30 and 9.30 AM.

Procedure
- Start by taking all the usual hygiene and first aid measures.
- In the case of contamination of skin that is intact: wash the area liberally with warm water and soap and then disinfect with a skin disinfectant: alcohol 70% or chlorhexidine 0.5% in alcohol 70%.
- In the case of a splash incident onto the skin or mucous membranes (eyes, mouth), the surface must be immediately and thoroughly rinsed with saline solution or water
- If the skin is punctured or cut: let the wound bleed freely if possible, rinse the wound or mucous membranes with water or saline solution and disinfect the wound with a skin disinfectant.
- In the case of injury or contamination of the mucous membranes, note all the available personal details of the source patient, if possible, for the VGM department.
- Contact the research staff at the VGM department **as soon as possible** on (071) 526 3643 or (071) 526 8015 or outside of office hours, please contact the internal medicine consultant on duty at the Accident and Emergency Department on (071) 529 9418, who will investigate whether any additional steps need to be taken to avoid infection with HIV, Hepatitis B, or Hepatitis C. If you have a needle stick incident outside of office hours, you must also notify the VGM department on the morning of the next working day on (071) 526 3643 or (071) 526 8015.

Collection of saliva samples Protocol

Important: Guidelines and methods of saliva collection depend on the type of research. Please consult the literature and always confirm with your supervisor which guidelines are to be followed. Should these deviate from this protocol, then you should discuss this beforehand with the research technicians at SOLO.

Supplies:

- Saliva collection tubes
- Labels
- Gloves
- Disinfectant

Guidelines for saliva collection:

- Always wear **gloves** when touching saliva tubes and other material that has been in contact with saliva;
- **Always label the samples.** Do not leave behind any unlabelled samples! Label the tubes **before** collecting any saliva. Use labels that can be frozen, so that they do not fall off the tubes in the freezer;
- **Disinfect** the outside of the tubes with an alcohol wipe after securing the lid and before they are stored;
- Follow the instructions provided with the sample collection equipment.

Sample contamination

Instructions for preventing contamination of the sample:

- No alcohol consumption for 12 hours prior to the saliva collection;
- No food or drink, except for water, for a minimum of 1 hour (preferably 2 hours) beforehand;
- Ideally no water directly before collection of the saliva sample. If necessary, the participant may rinse his/her mouth with water. Wait at least 10 minutes after rinsing before collecting the saliva to prevent thinning of the sample;
- Document the participant's consumption of alcohol, caffeine, nicotine and medication.

The samples can also be contaminated by blood. This can be problematic, as many of the values that are tested for can be found in the blood in higher concentrations.

Instructions to prevent contamination of the sample with blood:

- Ensure the participant does not brush his/her teeth for at least 45 minutes before the sample is taken;
- No visits to the dentist for a minimum of 48 hours prior to the saliva sample being collected;
- Screen the participant beforehand for oral health and oral damage/injuries;
- Saliva samples that are visibly tainted by blood must not be used for analysis.

Guidelines for storage of samples:

- Think carefully about how and where the sample will be stored before the start of the study and before any saliva samples are collected. Some substances cannot be kept at room temperature. The guidelines on freezing/storing samples depend on the type of research. Consult the literature and always confirm the guidelines to be followed with your supervisor;
- Generally, it is advisable to freeze saliva samples as soon as possible after collection at a temperature of -20^{o}C or below. If this is not possible, keep the samples cooled (4^{o}C) and place them in a freezer as soon as possible (ideally within 2 hours);
- Make sure the samples do not defrost and subsequently refreeze;
- If you keep samples in the -80^{o}C freezer, do not touch the freezer without wearing protecting gloves, not even the doors or the drawers.

Saliva collection methods

There are different methods for collecting saliva. These methods can broadly be divided into passive drool, and absorbent material.

Below a number of examples are given of collection methods with different types of equipment. Please note: there are different collection supplies on the market. The method to be used depends on the equipment used; always check the instructions provided with the equipment. The method also depends on the type of research to be done and the substances that are to be measured.

Put all the supplies out on a tray. Ensure that the collection tube can be partially or completely upright after collection. Wear gloves when collecting the sample and allow the participant to wipe his/her mouth with a cloth afterwards if they want to, drink some water, and possibly wash their hands.

Passive drool technique

- Take the top off the saliva tube;
- Give the participant the tube and ask them to spit into the tube.
- Afterwards, replace the cap on the tube.

Absorbent material

Swab stick: use with babies

- Take the swab out of the wrapper.
- Put the stick in the baby's mouth for around 1 minute. It is important to keep monitoring the baby's mood. If the baby becomes fractious, you should stop;
- Put the stick in the tube.

Salivette cotton swab: use on adults

- Remove the cap from the tube and take the sponge out of the tube;
- Get the participant to keep the sponge in their mouth for at least 1 minute;
- Ensure that the sponge is put in the innermost tube afterwards;
- Put the cap back on the tube afterwards.

Nutritional supplements

General

Within the FSW it is possible to carry out research in which nutritional supplements are administered to participants (for example, L-dopa, oxytocin or Tyrosine). When a study involves high doses of supplements, medicines, or psychotropic substances it is possible that it cannot take place in the FSW, but will have to be moved to the LUMC. Medicines can only be administered in collaboration with the pharmacy.

Some general tips:

- Take the into account how long it is before the supplement or medicine will take effect;
- When administering supplements/food/drinks, use disposable materials whenever possible, such as disposable cups and individual juice carton, instead of a large carton which then has to be kept in the fridge for an extended period of time;
- When medicines need to be kept, do this in a cupboard that can be closed and locked;
- When supplements / food / drink need to be chilled, it is important to keep these in the designated fridge. If in doubt, always consult the lab coordination/SOLO. Food and drink may NOT be kept in a fridge in which bio samples are also kept;
- Ensure that you clean up after any spillages of supplements/food/drink.

Scent research

General

Research involving scent can be carried out in many different ways. A number of options are mentioned below. It is important to have a discussion with the lab coordinator/SOLO before the start of the study to establish whether the type of study planned is suitable in the lab. Smells that linger in the lab could compromise subsequent studies.

Automatic scent diffuser

If the aim is to fill the room with a smell, an automatic scent diffuser can be used. This can be filled with essential oil or aroma oil. The diffuser can be place out of sight of the participant in order to diffuse a smell without their knowledge. Switch the diffuser on well before the participant arrives, to ensure the smell has spread throughout the room. After every participant, you should clean the diffuser and refresh the water.

Scent inhaler

Another method is to give the participant something to actively smell. This can be done with a scent inhaler. As there is contact between the equipment and the participant in this method, it is important for hygiene regulations to be followed. Clean the inhaler thoroughly after each participant and ensure that the parts that the participant came in contact with are disinfected.

Guidelines for the setup of science areas

Storage of collected body tissues and cells

General:

- Body tissues and cells that have been collected can be briefly stored in a fridge or freezer at the science lab behind a closed door;
- Body tissues and cells may only be stored long-term in freezers installed in a room with restricted access, or in a locked freezer;
- Body tissues and cells may only be used for other studies than those the participant took part in if the participant has given his/her informed consent;
- Body tissues and cells may only be stored long-term if this has been stated in the research protocol approved by the METC (or internal ethics committee), and with the participant's informed consent;
- Stored body tissues and cells should be labelled in such a way that the origin of the sample can always be traced.

There are some guidelines for storage in and use of freezers (-20 and-80), detailed below. .

Maintenance of the space:

The freezer room (4.B04) is maintained by Location Management. The room may only be set up or rearranged in conjunction with the FSW Location Management.

Access:

To gain access to the freezer room (4.B04) you will need a key. The head of the laboratory should request one from the facilities management.

Use of the space:

The users of the space are responsible for keeping it clean, on, under and around the freezers. All materials brought into the freezer room must either be stored in the freezer, or taken back out of the freezer room. Nothing may be left on, under or around the freezer without permission from the caretaker.

Equipment:

The users of the freezers are at all times personally responsible for the optimal functioning of the freezers. All freezers must have a completed "what to do and who to call" form for use in case of malfunction. The user is responsible for checking and adjusting the contact details on this form from time to time. Location Management will maintain the infrastructure, such as the pipes, emergency power supply, connection to BMS, and checks on log and alarm notifications.

In case of malfunction: call (071) 527 3701

Back up freezer(s):

In the event of a -80 freezer breaking down or needing to be cleaned, there is the option for the users to temporarily store their samples in the back-up freezer (including sample records). If the

back-up freezer is put to use, the user must complete the form on the back-up freezer and inform Location Management. If this has not been done, the supervisor is entitled to remove the stored samples immediately. The user is responsible for ensuring that the period of use is kept to a minimum and will inform Location Management when the back-up freezer is empty again. After use, the back-up freezer must be cleaned and defrosted by the last user, so that it is immediately ready for temporary use again.

Cleaning:

Users are personally responsible for the cleaning of the freezer(s). Cleaning entails removing all samples from the fridge that are no longer in use for research (to be destroyed or kept in external storage), and removing ice and condensation from the inside of the freezer and the door.

Responsibility:

The responsibility for following these rules lies with the department that has purchased the freezers and/or with the users (researchers) who make use of a freezer in the freezer room (4.B04). Possible consequences of (frequently) breaking these rules can include a temporary withholding of approval for requested purchase of additional freezers, or charging cleaning costs to the department's SAP code.

Research equipment

For research involving participants only the measuring equipment purchased and maintained by SOLO may be used. This equipment must comply with the standard requirements and regulations for use by researchers on participants. The equipment that has been purchased is easy to use, which means students can also work with it once they have been trained. The equipment will only be purchased from reputable and experienced manufacturers and suppliers. SOLO will ensure that all equipment has an identification label and will run a visual and electrical inspection test on it annually. The test results will be documented by SOLO.

Equipment supported

	Type of data	Power supply	Isolation from mains	inspection
BioPac MP system	physiology	External IEC60601-1 specified power supply (AC150A).	Galvanised and/or INISO	SOLO
BioPac BioNomadix	physiology	Battery	N/A	SOLO
BioSemi Active Two	EEG	Battery	optic	SOLO
BMEye	Blood pressure	Mains	mains: none BioPac: INISO	SOLO
Digitimer DS5	Electrical stimulator	Mains. Check jumpers at the rear of the device		Digitimer*
Digitimer DS7	Electrical stimulator	Mains		SOLO
EGI NetStation	EEG	Mains	optic	SOLO
Eyelink	eye tracking	Mains	No physical contact	SOLO
Nexfin	Blood pressure	Mains	mains: none BioPac: INISO	SOLO
Tobii T120	eye tracking	Mains	No physical contact	SOLO
Tobii X2-60	eye tracking	Mains	No physical contact	SOLO
Tobii X3-120	eye tracking	Mains	No physical contact	SOLO
Tobii Glasses 2	eye tracking	Battery	mains: N/A BioPac: INISO	SOLO
VUAMS 5fs	Physiology	Battery	optic	SOLO

*Inspection every 2 years

Safety inspection

All electrical equipment used during the study will be inspected regularly (once a year) by SOLO for electrical safety and general state of repair. This is in line with the regulations in the NEN-EN-IEC 62353:2014 guideline Medical electrical equipment – Periodic testing and testing after repair. If either the knowledge or the necessary diagnostic equipment is lacking at SOLO, the device will be submitted to the supplier or manufacturer for checking and/or inspection. Should the safety of the equipment be in doubt in-between inspections, or the device have displayed a fault, a compulsory inspection will need to be done in-between times. Equipment which is to be used outside of the laboratories must be recalled to FSW once a year for the regular inspection.

Inspection

The electrical inspection may only be carried out by an NEN-EN-IEC 62353 certified member of SOLO staff, or by the supplier or manufacturer of the device. The SOLO research technician has been trained and certified to carry out this inspection according to the guidelines of the NEN-EN-IEC 62353:2014 Medical electrical equipment.

Rejects

Should the equipment fail the electrical inspection or be in a state that may cause an unsafe situation, the equipment will be immediately taken out of service. If the equipment is unsafe, SOLO will if possible immediately have it repaired, or otherwise removed.

Once the equipment has been repaired according to the manufacturer's standards and the regulations as described in the NEN standards, a reinspection will have to take place.

Identification

All equipment (including battery powered) used during a study, must be marked with a unique identification label which allows the serial number, history, date of purchase, any repairs, logs etc. to be found in the SOLO database.

For equipment that has undergone electrical inspection according to NE-EN-IEC 62353, the regular inspection reports must be stored in the SOLO database. The log books in the laboratory will only record the inspection date.

Equipment without an identification label may not be used in the labs without prior permission from SOLO.

Use of equipment
In order to support researchers in their use of the science facilities and research equipment, SOLO's research and lab technicians have been trained to provide explanation, and video clips have been created explaining how to operate the equipment.

Competent and qualified
Members of staff and students may use medical electrical equipment on participants only if they are competent and qualified to use the equipment. Proof of competence and qualification must be presented to the lab coordinator before the start of the study.

Disinfection and cleaning of equipment components
The equipment will be cleaned by SOLO during inspection. Should cleaning be needed in the interim, the lab coordinator can submit a request to SOLO.

The leads should be wiped by the study leader with an alcohol prep pad after each participant. Disposable items must be discarded in the appropriate bin.

Furniture

Furniture: informal setup in the laboratory. Tables, chairs, black-out material.
Research equipment: informal setup in the laboratory. Measurement equipment, scanners, PC with peripherals for acquiring and storing of participant data.
Medical equipment/instruments: informal setup in the laboratory. Research equipment and instruments for the collection of body tissues and cells, and storing data.

The furniture in the laboratory should be easy to move and easy to (keep) clean. It should be made of wood (smooth, varnished), metal and/or plastic. The height of the researcher's desk should be adjustable and the participant's chair can have arm rests (if desired).

What kind of furniture has been approved for use in laboratories?

- Furniture made of wood/steel/plastic with a smooth surface
- Height-adjustable furniture (researcher's table and desk chair)
- Furniture that is easy to move
- Furniture (chair) for participant
- Furniture to be used for venepuncture

What kind of furniture is not approved for use in laboratories?

- Any furniture that does not comply with the above, specifically:
    - Any upholstered furniture
    - Any furniture that swivels or has wheels

The FSW has chosen suitable chairs for adults. These chairs were bought from LKV and are available with or without arm rests. This is the LKV-E608, stackable, with and without arm rest, with separate seat and back rest, leather-upholstered and plastic chair tips. A desk chair has also been selected for the researcher.

The following are suitable chairs for children:

The children's barber chair "Cat" (available from various online shops) and the Stokke Tripp Trapp.

The right black-out material can be supplied and fitted by Roodenburg&vdMeel. This will usually need to be made to measure. SOLO is the point of contact.

NB. Fixed furniture (table fixed to the wall) should also be made of wood/steel/plastic, like the movable furniture, and should have a smooth surface. Joints must be sealed.

Support for scientific research (SOLO) Protocol

To be expanded

Research in labs Protocol

Lab coordinators

The lab coordinators are responsible for the day-to-day running of the laboratories, and are the first port of call for researchers who want to use the lab for research. The lab coordinators manage the diary, keep the keys to the labs, and ensure that the labs are tidy and clean. There is also information about each lab in the room, as well as the relevant safety instructions.

Lab adaptations

It is important for the lab coordinators to be made aware of everything that occurs in and around the labs. The lab technicians will only implement adaptations to the lab after consultation with the lab coordinator.

- Certain choices made by one researcher can also have an impact on others, for example, installing software on a lab PC. This could affect other programmes on that PC, which may in turn affect data collection in another study;
- Problems that a researcher may encounter could also affect others. In that case, a joint solution could be found.

Placing orders

- In order to streamline orders for the labs as much as possible, the lab coordinator will collect the lab orders for all the researchers;
- Preferably, the orders will be placed by the lab technicians, so that they can oversee which equipment (with a view to providing support) and products (with a view to the stock for different departments) are being used;
- The lab coordinator is informed by the technicians as soon an order has arrived.

Use of equipment

Before you start working with a piece of equipment, you must ensure that you know how to operate the device and how to connect the participant to the device. You must also know what the test signal should look like, so that before the experiment starts you can assess whether it will produce useable data or whether adjustments need to be made, for example to the placing of the electrodes. The chief researcher and lab coordinator are responsible for ensuring that researchers are sufficiently competent to carry out the research.

General preparations

Before the participant comes in ensure that all preparations are complete.

- Please make use of the sliding signs on the door, to make it instantly clear that the room is occupied;
- Tidy up the laboratory;
- Wipe the tables and chairs with a cloth;
- Check the necessary devices, leads, and electrodes for visible damage. Should you suspect that these are faulty, please contact your supervisor or, in case of his/her absence, SOLO lab support;

- Check the settings and if necessary the battery life of the device;
- Switch on the monitors before switching on the computers;
- Open the necessary software and check the communication for all devices;
- Place paper towels on the table to collect rubbish and gel;
- Ensure all necessary supplies are set out. Do not forget gloves, disposable electrodes, gel, Nuprep, cotton wool, etc.;
- Ensure that a log book is available for noting down particulars as and when needed;
- Put out the Informed Consent form ready to be read and signed.

As soon as there are two of you present, you can receive the participant and carry out the study. Ensure that you continue to work hygienically and safely throughout the study.

After the study, you must tidy away all the equipment used, switch off the devices and clean all reusable items that have come into contact with the participant. The tables and chairs must also be wiped with a cleaning cloth again. Ensure that no personal data is left behind on the computer in the lab.

Research on location Protocol

To be expanded

- Minimal SOLO support; rules to be drawn up.

Use of IncidinProtocol

Physiological measurements Protocol

Electrocardiography (ECG)

General information

An electrocardiogram measures the electrical activity of the heart muscle.

- ECG is measured in millivolt (mV);
- The ECG signal is usually between 1 and 5 mV.

Equipment needed:

- ECG equipment;
- 3 disposable electrodes (Ag/AgCl);
- Scrub gel (NuPrep);
- Cotton buds/cotton wool pads;
- Gloves;
- Alcohol wipes.

Cleaning/preparation

Important: Always wear disposable gloves when you clean the participant's skin, apply the electrodes, and disconnect the participant. After use, always remove the gloves and dispose of them.

It is important to reduce the impedance (resistance) of the skin before applying the electrodes, by removing oils and dead skin cells. It is recommended to use a scrub gel (NuPrep). The gel is gently rubbed on the skin with a cotton bud or pad. Afterwards, the skin is dried with a clean cotton pad. Apply the electrodes directly after cleaning the skin.

Placing the electrodes

Important when using Biopac devices: when attaching the leads, you must squeeze the plastic lock connector at the end of the lead. When disconnecting the leads, squeeze the lock connector again. Never pull on the lead itself. This material is very fragile and breaks easily. Similarly, when the leads need to be attached to or detached from the wireless module, you should use the plastic squeezable connector and refrain from pulling on the leads. Afterwards, loosely coil the leads and tuck them into the appropriate pocket. Do not knot or twist the leads, as it may damage them.

Important: Apply the electrodes 5 to 10 minutes before you start measuring.

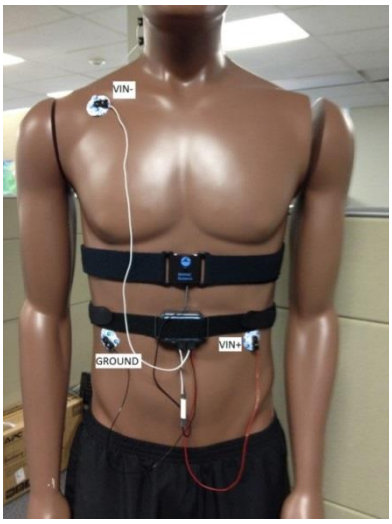
The number of electrodes used and their placement can differ depending on the type of study. A common method is to use three electrodes, one of which is placed under the right collarbone (negative, V-), one on the left on the bottom rib (positive, V+), and one on the right just below the ribs (grounding).

Which leads (specifically: which colour) should be attached to these electrodes depends on the system that you are working with. With the Biopac system, you should attach the black lead to the grounding electrode on the right, below the ribs. The red lead should be attached to the electrode on the left, on the ribs, and the white lead to the electrode on the right, below the collarbone. When using the wireless Biopac module, you can fix the strap with the transmitter around the participant's

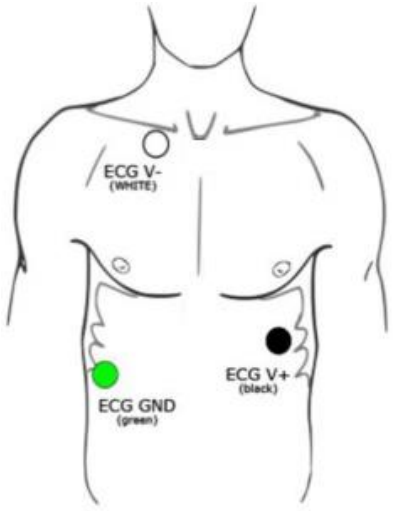
waist and then attach the leads to the electrode. Ensure the strap is placed between the Biopac transmitter and the skin, so that the transmitter does not come into contact with the skin.

With the VU-AMS system, you attach the green lead to the grounding electrode on the right, below the ribs. The black lead should be attached to the electrode on the left, on the ribs, and the white lead to the electrode on the right, below the collar bone.

In both systems, the heart should be in the centre of a line drawn from the positive to the negative electrode. The ground electrode must never be placed between these two!



Biopac



VU-AMS – Figure adapted from source: Nederend, ten Harkel, Blom, Berntson, & de Geus, 2017

Afterwards

Remove the leads and, if present, the wireless module. The participant can then remove the electrodes him/herself. Removing the electrodes can be painful for some people. Depending on the sensitivity of the participant's skin, there may be red marks visible. These will normally fade within a few hours. Give the participant a tissue to remove any excess gel, or allow the participant to wash the areas in question with water and soap. The electrodes can be discarded in the bin. After each participant the equipment he/she has been in contact with must be cleaned. This could apply to the leads that were attached to the electrodes and, in the case of the wireless Biopac module, the transmitter. Clean these components carefully with an alcohol wipe. Ensure that no liquids enter the equipment. The strap must be cleaned after use with Incidin.

Tips to ensure usable data

- Check whether the electrodes and leads are attached properly;
- The participant must move as little as possible to prevent artefacts in the data;
- The participant must be comfortable and sit in a natural posture with both feet on the floor;
- When the data looks irregular or shows a flat line, check whether the leads are properly attached and whether the electrodes are still properly attached;
- If the data looks upside down (i.e., when the R peaks are pointing down) it is likely that the V+ and V- leads have been swapped around. Check whether the V- lead is attached to the

electrode under the collarbone and the V+ lead to the electrode on the left-hand side below the bottom rib.

Literature

Nederend, I., ten Harkel, A. D. J., Blom, N. A., Berntson, G. G., & de Geus, E. J. D. (2017). Impedance cardiography in healthy children and children with congenital heart disease: Improving stroke volume assessment. *International Journal of Psychophysiology, 120,* 136-147.

Electrodermal response (SCL/EDA/GSR)

General information

When you measure electrodermal response, you are measuring how 'well' the skin conducts electricity. Often the skin will conduct electricity better during higher arousal.

- Electrodermal response is measure in micro Siemens (µS);
- Electrodermal response levels usually vary between 2-20 µS.

Necessary equipment

- 2 disposable electrodes (see picture; the electrodes for measurements such as ECG and ICG cannot be used for this);
- If necessary, isotonic gel.

Cleaning/preparation

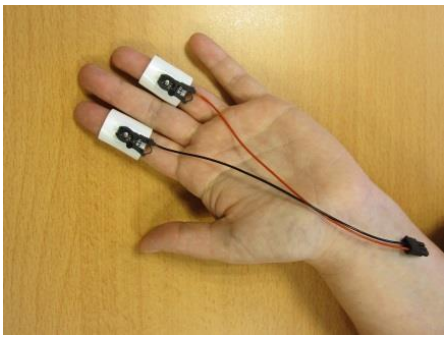
Do not clean the skin beforehand using alcohol, abrasive substances (such as scrub gel), or soap. If the participant needs to wash his/her hands, just use lukewarm water **without** soap. The disposable electrodes come with gel, but should they be dry isotonic gel can be applied.

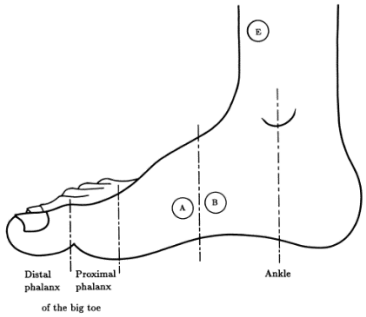
Placing the electrodes

Important when using Biopac: when attaching the leads, you must squeeze the plastic lock connector at the end of the lead. When disconnecting the leads, squeeze the lock connector again. Never pull on the lead itself. This material is very fragile and breaks easily. Similarly, when the leads need to be attached to or detached from the wireless module, you should use the plastic squeezable connector and refrain from pulling on the leads. Afterwards, loosely coil the leads and tuck them into the appropriate pocket. Do not knot or twist the leads, as it may damage them.

Important: Place the electrodes at least 10 minutes before you start taking measurements, so as to allow the gel to work.

The placing of the electrodes can depend on the type of research. Before the start of the research project you should consult the literature and discuss the best approach with your supervisor. The best signal is measured on smooth, hairless skin. Active electrodes are placed on the inside of the fingers of the non-dominant hand (see figure). The electrodes can be attached to the distal phalanges (fingertips), as there is a greater responsiveness and the greatest sweat gland activity in that area. Another option is to attach the electrodes to the middle phalanges, as the fingertips are often callused. Place the electrodes on the index finger and middle finger, or on the index finger and ring finger. After you have attached the disposable electrodes you can attach the leads to the electrodes. It does not matter which leads you attach to which fingers. If using the Biopac module, you can attach the strap with the transmitter to the participant's wrist before attaching the leads to the electrodes. Ensure that the strap is placed between the Biopac transmitter and the skin, so the transmitter does not make contact with the skin.





When neither hand can be used (for instance if both hands are needed for the experiment, or with babies who are likely to pull on the electrodes), the inside of the foot can be used. In this case, the electrodes are placed on the musculus abductor hallucis (big toe abductor), bordering on the sole of the foot and halfway between the proximal phalanx of the big toe and the spot directly below the ankle (see figure, electrodes A and B). For more information about possible sites for measuring electrodermal response, see van Dooren, de Vries, and Janssen (2012).

Calibration

In the case of EDA it is necessary to calibrate before carrying out measurements. How this is done will differ according to the type of equipment. Always check how this should be done.

Afterwards

When you are finished, remove the leads and, if using, the wireless modules. The participant can then remove the disposable electrodes him or herself, and wash hands. The disposable electrodes can be disposed of in the bin. After each participant, you should clean any equipment that has been in contact with the participant. This may apply to the leads that were attached to the electrodes and,

if using the wireless Biopac module, the transmitter as well. Clean these components carefully with an alcohol wipe. The strap must be cleaned after use with Incidin.

Tips to ensure useful data

- Check whether the electrodes and leads are attached properly;
- The participant should breathe slowly and regularly;
- The participant must move as little as possible to prevent artefacts in the data;
- The participant must be comfortable and sit in a natural posture with both feet on the floor;
- Before you start, ask the participant to hold his/her breath briefly. That way you can check whether you are getting a good signal and whether the electrodes are attached properly;
- When the data looks irregular or shows a flat line, check whether the leads are properly attached and whether the electrodes are still properly attached;
- If the quality of the data remains poor, it could be that the participant is a non-responder. This occurs in 10% of people.

Literature

Boucsein, W., Fowles, D. C., Grimnes, S., Ben-Shakhar, G., Roth, W. T., Dawson, M. E., & Filion, D. L. (2012). Publication recommendations for electrodermal measurements. *Psychophysiology, 49,* 1017-1034.

Van Dooren, M., de Vries, J. J. G., & Janssen, J. H. (2012). Emotional sweating across the body: Comparing 16 different skin conductance measurement locations. *Physiology & Behavior, 106,* 298-304.

https://www.biopac.com/webinars/eda-faq/

Facial Electromyography (fEMG)

General information

- fEMG is measured in millivolt (mV)

Necessary equipment

- fEMG machine
- 5 electrodes (not disposable electrodes)
- Electrode stickers (size small)
- Electrode gel (Signa gel)
- Plastic syringe
- Scrub gel (NuPrep)
- Cotton bud/cotton wool pads
- Gloves
- Alcohol wipes

Cleaning/preparation

You can put the gel on the electrodes before the participant arrives. Fill the syringe with a little electrode gel. Then fix the electrode stickers to the electrodes, so that the hole in the sticker is above

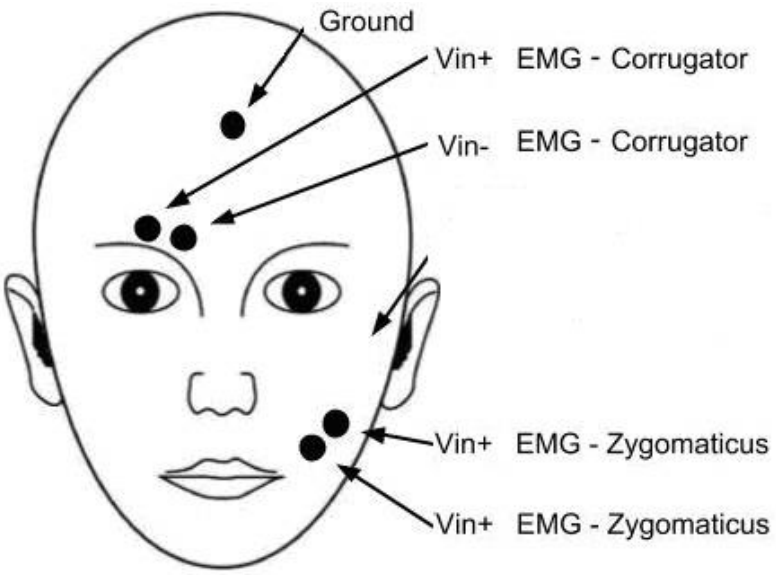
the electrode cavity. Next, squirt a little electrode gel into the cavity. It is best to use a syringe made entirely of plastic for this. Ensure that the electrode cavity is filled entirely with gel, but that it does not overflow. Just before you apply the electrode, remove the protective plastic from the sticker (achieving this while wearing gloves requires practice).

Important: Always wear disposable gloves when you clean the participant's skin and apply the electrodes. After use, remove the gloves and dispose of them.

Before applying the electrodes it is important to reduce the impedance (resistance) of the skin by removing oils and dead skin cells. It is recommended to use a scrub gel (NuPrep). The gel is gently rubbed onto the skin using a cotton bud or pad. Afterwards, the skin is dried with a clean cotton pad. Apply the electrodes directly after cleaning the skin.

Placing the electrodes

fEMG often measures the corrugator supercilii muscle ("frowning" muscle) and the zygomaticus major muscle ("smiling" muscle). In order to measure these, you will need 5 electrodes. Place two electrodes on the zygomaticus major. It is situated along the imaginary line from the corner of the mouth to the ear (see picture). Place two electrodes on the corrugator supercilii, which is just above the eyebrow. Place 1 electrode at just about the start of the eyebrow and 1 electrode a little further along (around 2cm) just above the eyebrow. The last, grounding electrode can be applied in a variety of different places, but the recommendation is to place it in the middle of the forehead just below the hairline.



If you are using the wireless Biopac system (BioNomadix) you can attach the strap with the transmitter to the participant's head. Ensure that the strap is between the Biopac transmitter and the skin, so that the transmitter does not make contact with the skin. Then attach one pair of leads (red/white) to the corrugator electrodes and one pair to the zygomaticus electrodes. The red lead

should be attached to the outer electrodes and the white leads to the inner electrodes. Attach the black lead to the grounding electrode.

Important when using Biopac devices: when attaching the leads, you must squeeze the plastic lock connector at the end of the lead. When disconnecting the leads, squeeze the lock connector again. Never pull on the lead itself. This material is very fragile and breaks easily. Similarly, when the leads need to be attached to or detached from the wireless module, you should use the plastic squeezable connector and refrain from pulling on the leads. Afterwards, loosely coil the leads and tuck them into the appropriate pocket. Do not knot or twist the leads, as it may damage them.

Afterwards

Remove the leads and the wireless module. You can then carefully remove the electrodes. Removing the electrodes can be painful for some people. Depending on the sensitivity of the participant's skin, there may be red marks visible. These will normally fade within a few hours. Give the participant a tissue to remove any excess gel, or allow the participant to wash the areas in question with water and soap.

Remove the electrode stickers from the electrodes and dispose of them. Clean the electrodes as soon as possible after us. Dried-up gel is more difficult to remove and diminishes the electrical contact with the skin. Run the electrodes under a luke-warm tap and use a soft toothbrush to gently remove the gel out of the cavity. Do not immerse the electrodes in a solution. Ensure that all the gel has been removed. After cleaning, dry the electrodes thoroughly with a paper towel before tidying them away. After each participant, you should also clean the equipment that has been in direct contact with the participant. This could be the leads that were attached to the electrodes and, in the case of the wireless Biopac module, the transmitter and the strap. Clean these components carefully with an alcohol wipe. Ensure that no liquid gets into the equipment. The strap must be cleaned after use with Incidin.

Tips to ensure useful data

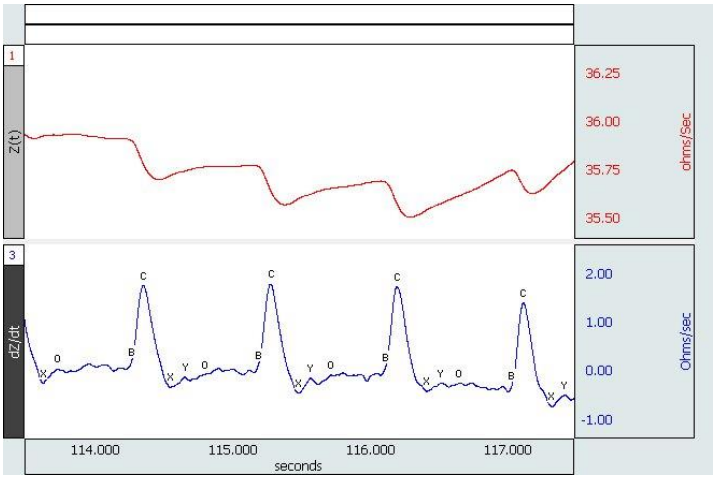
- Check the electrodes and the leads are properly attached;
- Before you start the experiment, ask the participant to smile and frown briefly. This will allow you to check if you get a signal and whether the electrodes are placed correctly.

Impedance cardiography (ICG)

General information

ICG measures the electrical impedance (resistance) of the blood in the thorax (chest), specifically in the aorta. This impedance depends on the blood levels in the aorta. Every heartbeat shows a change in impedance. When blood levels are high (directly after the opening of the aorta valve in the heart) the impedance is low. The ICG signal (Z(t)), as well as its derivative (dZ/dt) are used to calculate various hemodynamic parameters, such as stroke volume, cardiac output and the pre-ejection period.

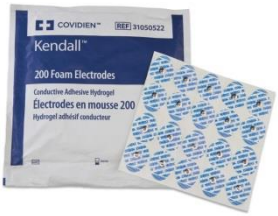
- ICG is measured in ohms/sec



Source figure: https://www.biopac.com/application/icg-impedance-cardiographycardiac-output/

Necessary equipment

- ICG devices;
- Disposable electrodes (Ag/AgCl)
  (the amount is dependent on placement method);
- Scrub gel (NuPrep);
- Cotton buds/cotton wool pads;
- Gloves;
- Alcohol wipes.



Cleaning/preparation

Important: Always wear disposable gloves when cleaning the participant's skin, applying electrodes or when you disconnect the participant. After use, you should always remove them and dispose of them.

When placing the electrodes it is important to reduce the impedance (resistance) of the skin by removing oils and dead skin cells. The recommended method for doing this is with a scrub gel (NuPrep). The gel is gently rubbed on the skin with a cotton bud or a cotton pad. Then the skin is dried with a clean cotton wool pad. Place the electrodes directly after cleaning the skin.

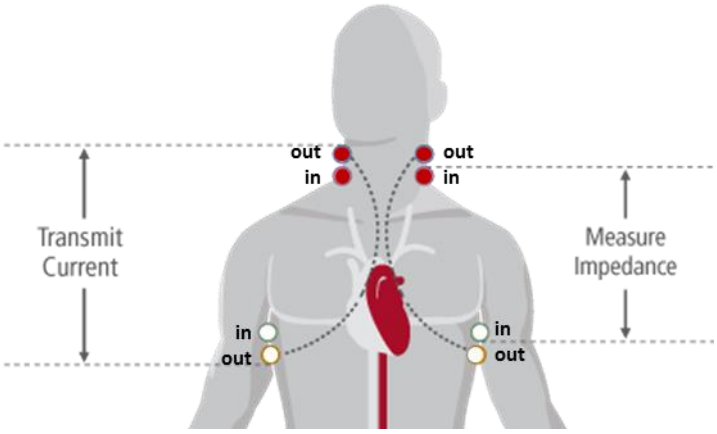
Placing of the electrodes

Important when using Biopac devices: when attaching the leads, you must squeeze the plastic lock connector at the end of the lead. When disconnecting the leads, squeeze the lock connector again. Never pull on the lead itself. This material is very fragile and breaks easily. Similarly, when the leads need to be attached to or detached from the wireless module, you should use the plastic squeezable connector and refrain from pulling on the leads. Afterwards, loosely coil the leads and tuck them into the appropriate pocket. Do not knot or twist the leads, as it may damage them.

Important: Place the electrodes 5 to 10 minutes before you start taking measurements.

The number of electrodes used and the placing of the electrodes differ depending on the research. In general, there are two different methods for placing electrodes in ICG studies (explained below). In addition to these methods there are other ways to apply electrodes.

Method 1 (e.g. Biopac)



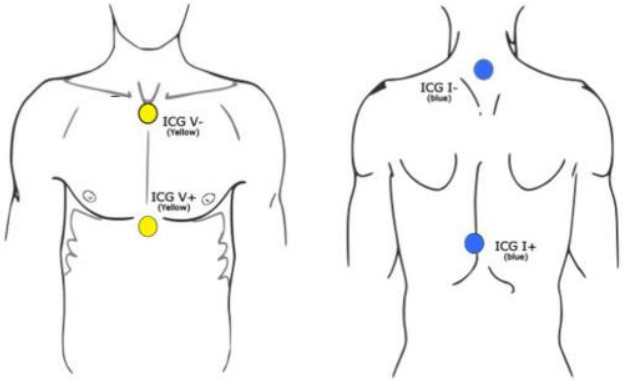
Biopac – Edited figure from source: https://medis.company/cms/index.php?page=icg-impedance-cardiography

For this method, eight disposable electrodes are used. Four of these electrodes are placed in the neck, two on the left hand side and two on the right hand side. These pairs are placed over the neck artery with 5 cm between the electrodes (measured from the centre of the electrodes). The other 4 electrodes are placed on the ribs, two on either side. Each pair is placed high up on the rib cage (for women just below the bra strap) and in line with the centre of the shoulder. In addition, the electrodes must be placed 5 cm apart (measured from the centre of the electrodes).

For this method, you will need 4 pairs of leads, two pairs of red leads and two pairs of white leads. The red leads need to be attached to the electrodes in the neck. The red “out” leads should be attached to the upper electrodes, the red “in” leads to the lower electrodes. The white leads are attached to the electrodes on the chest. You should attach the white “out” leads to the lower electrodes, the white “in” leads should be attached to the upper electrodes. A tip for remembering the leads is that the “in” leads always connect to the electrodes closest to the heart.

When using the wireless Biopac module, you can fasten the strap with the transmitter to the participant’s waist and then attach the leads to the electrodes. When doing this, please make sure the strap is placed between the Biopac transmitter and the skin, so the transmitter does not make contact with the skin.

Method 2 (e.g. Vu-AMS)



VU-AMS – Edited figure from source: Nederend, ten Harkel, Blom, Berntson, & de Geus, 2017

In this method, four electrodes are used. Two electrodes are fixed to the chest, one just above the sternum and one just below the sternum. The other two electrodes are placed on the back, three centimetres above and three centimetres below the electrodes on the chest. The yellow leads are attached to the chest, the short one to the lower electrode and the long one to the higher electrode.

Afterwards

When you are finished, remove the leads and, if using, the wireless modules. Then the participant can remove the electrodes him or herself. Removing the electrodes can be painful for some people. Depending on the sensitivity of the participant's skin, there may be red marks visible on the skin. These will normally fade within a few hours. Give the participant a tissue to remove any excess gel or allow the participant to wash the areas in question with water and soap. The disposable electrodes can be disposed of in the bin. After each participant, you should clean any equipment that has been in contact with the participant. This may apply to the leads that were attached to the electrodes and, if using the wireless Biopac module, the transmitter as well. Clean these components carefully with an alcohol wipe. The strap must be cleaned after use with Incidin.

Tips to ensure useful data

- Check whether the electrodes and leads are attached properly;
- The participant must move as little as possible to prevent artefacts in the data;
- The participant must be comfortable and sit in a natural posture with both feet on the floor;
- When the data looks irregular or shows a flat line, check whether the leads are properly attached and whether the electrodes are still properly attached;

Literature

Nederend, I., ten Harkel, A. D. J., Blom, N. A., Berntson, G. G., & de Geus, E. J. D. (2017). Impedance cardiography in healthy children and children with congenital heart disease: Improving stroke volume assessment. *International Journal of Psychophysiology, 120,* 136-147.

Electro-encephalography (EEG)

General information

EEG measures the electrical activity in the brain. More specifically, it measures the sum of all post-synaptic potentials of the neurones in the cerebral cortex. This signal is very weak and is therefore measured in microvolt (µV).

- Below is a brief overview of the procedure for applying and removing electrodes for EEG research. Before you start doing EEG research, however, it is important that you are trained to perform this procedure. Ensure you have mastered all the steps and that you are confident in what you are doing;
- There is a wide range of different EEG equipment. The explanation below is aimed at studies that make use of BioSemi devices with active electrodes.
- The procedure can overwhelm the participant. It is important to give the participant enough information about and during the procedure and to make sure that he/she feels at ease.
- How many loose electrodes are used and how many in the cap is dependent on the study. Consult the literature or your supervisor if you are unsure of how many electrodes to use and where to attach them.

Necessary equipment

- Electrode array;
- Loose flat electrodes;
- CMS/DRL electrodes;
- Electrode cap including chin straps;
- Electrode stickers;
- Syringe with a blunted hollow needle;
- Electrode gel (Signa gel);
- Scrub gel (NuPrep);
- Alcohol wipes;
- Cotton buds/cotton pads;
- Tape measure;
- Leukopor tape;
- Paper towels;
- Disposable gloves.

General preparation

Ensure that all the necessary equipment is to hand and that all the preparations have been made before the participant arrives.

Fill the syringe with electrode gel (Signa gel). This works best if you put the syringe on the tube of electrode gel and then squeeze the tube at the same time as pulling on the syringe. This prevents air bubbles in the syringe. Attach the needle to the syringe. Ensure that the syringe does not come into contact with the tube of electrode gel again once contact has been made with the participant.

Stick the electrode stickers onto the flat electrode in such a way that the hole in the sticker is over the brown/grey part of the electrode.

Cut up some strips (around 10) of Leukopor tape, ready for use.

Preparing the participant
Important: Always wear disposable gloves when you clean the participant's skin and stick on the electrodes. After use, always take the gloves off and dispose of them. Before the electrodes can be placed, it is important to reduce the impedance (resistance) of the skin by removing oils and dead skin cells.

Sticking loose flat electrodes
You should always start by placing the flat electrodes. Squirt a drop of electrode gel onto the conductive brown/grey part of the electrode, within the ring of the sticker. It is important here that the needle on the syringe **DOES NOT** touch the conductive part of the electrode. This can damage the electrode.

Prepare the site where you are planning to apply the flat electrode. This can be done with scrub gel or alcohol wipes. The gel should be gently rubbed over the skin with a cotton bud or a cotton wool pad. Afterwards, the skin should be dried with a clean cotton wool pad. If you use the alcohol wipe, rub the wipe gently over the skin. Take care that no alcohol or scrub gel gets into the eyes when cleaning the area around the eyes. Place the electrodes directly after cleaning the skin. Place the electrodes on the face in such a way that the leads run towards the ears, allowing you to run them over the participant's ears. Then stick a strip of Leukopor tape on the electrode to prevent it from becoming detached. Once all the loose electrodes have been applied, you can fix the leads to the participant's shoulders with some Leukopor tape. Make sure the leads are not pulled tight anywhere and that there is enough room for them.

How many flat electrodes are placed and where depends on the research project. It is usual to place four electrodes around the eyes to register eye movements including blinking. To do this, you place two electrodes above and below an eye, and two electrodes on either side of the head, next to the eyes, on the outside of the eyes. Two more electrodes can be placed behind the ears (mastoid), and their signal can be used as grounding later.

Fitting the electrode cap

After the loose, flat electrodes have been placed, you should fit the electrode cap. There are different electrode caps that differ in the number of electrodes that can be placed, as well as in size. The most commonly used caps are yellow (50 - 54cm), red (54 - 58cm) and blue (58 - 62cm). Measure the circumference of the head along the forehead and the inion. The **inion** is the protuberance at the back of the skull. Use an appropriately sized cap. If in doubt, choose a tighter electrode cap, as long as this is comfortable for the participant. Attach the chin straps to the rings of the cap. Fix the cap onto the participant's head and secure the straps. If a strap is too tight, an extra strap can be added in. Ensure that the ears stick out of the cap. Measure the distance between the inion and the nasion. The **nasion** is the depression between the eyes. Shift the cap to ensure that the Cz electrode is exactly in the centre between the inion and the nasion. Make sure that you are holding the entire cap when moving it and not just an electrode hole. Then measure the distance between the two ears and move the cap in such a way that Cz is also exactly in the middle between the ears. Finally, check that the cap is not askew.

Connecting the electrodes to BioSemi devices

Plug the loose flat electrodes into EX1 - EX8 in the BioSemi AD-box. Then plug in the CMS/DRL array. These two electrodes serve as grounding and reference point. Should the array consisting of the two electrodes CMS and DRL be used, these will need to be plugged into the BioSemi box at the front. If an electrode array that includes the CMS/DRL is used, you must plug these in to the top in A. Then plug in all the electrode arrays that you are using. If you are using 32 electrodes, you will need one array which you plug into the BioSemi box in A. With 64 electrodes, you use 2 arrays, which you plug into A and B and with 128 electrodes you use 4 arrays, which you plug into A-D. Regardless of how many electrodes you place, you should only ever attach one pair of CMS and DRL electrodes. Also, please be aware that not all configurations are suitable for measuring with 64 or 128 electrodes. Now switch on the BioSemi AD-box.

Placing the electrodes in the electrode cap

Finally, place the electrodes in the electrode cap. Before attaching an electrode to the cap, the skin underneath the electrode must be prepared. You do this using the blunted needle on the end of the syringe with the electrode gel. Stick the needle through the hole where the electrode is to be attached until you feel skin. Scrape gently across the scalp with the needle without applying pressure. It is important that you do not hurt the participant, but that you do make contact with the scalp. In doing this, you are getting the hair out of the way and reducing the impedance of the skin. This requires some practice. After scraping the skin, squirt a little gel into the hole. This should be enough to make contact between the electrode and the skin, but not so much as to cause low impedance bridges. While applying the gel, press down on the plastic around the hole to avoid applying too much gel. Then press the electrode into the hole. Repeat this process for each electrode.

Start with the CMS and DRL electrodes. These electrodes are used as grounding and reference. On the front of the BioSemi AD-box there is a blue light that needs to be on continuously if the CMS and DRL electrodes have been placed correctly. If this light is blinking, it means there is a problem with one or more electrodes. Check the CMS, DRL and loose flat electrodes. If the light is steady, connect the other electrodes one by one. If the blue light starts blinking after attaching one of the electrodes, this can mean different things. It could be that not enough gel has been used, in which case no

contact can be made. Or it is possible that too much gel has been used, creating a bridge of gel which causes connectivity between two or more electrodes. So it is important to use neither too little nor too much gel. A third option is that the electrode is broken. If the light is blinking, try attaching the electrode again.

Afterwards

Remove all the electrodes from the BioSemi AD-box. Ensure that this happens in the correct way, so that the leads and connectors are not damaged. Then remove all the electrodes from the participant. You can opt to remove the cap including the electrodes from the participant's head first and remove the electrodes from the cap later. Do be careful not to break off any electrode tips! Allow the participant time to wash his or her hair and face.

Check whether the BioSemi box needs to be charged. To charge, connect the BioSemi box to the battery charger.

Cleaning

Dispose of all single use materials (tape, cotton buds, gloves etc.) in the bin. Do NOT throw the needle in the bin. This must go into a separate, dedicated sharps container.

Use warm water with detergent (Ivory detergent) and a toothbrush to wash the gel off the electrodes. Do not let the electrodes come in contact with metal. Also make sure that no water runs into the connectors. Don't forget to clean the cap thoroughly. Use a toothbrush or a small wooden stick to get all the gel out of the electrode holes. It can be useful to turn the cap inside out for this, so that you can reach easily. Make sure that you clean every hole and that all gel is removed. Remnants of dried-up gel can cause big problems when the cap is next used.

Disinfecting

Incidin is used for disinfecting. Incidin contains aggressive substances. It is recommended that you wear gloves, safety goggles and a lab coat while cleaning. Always read the instructions that are displayed in the labs thoroughly. Rinse the electrodes and electrode cap thoroughly with water after they have soaked in the Incidin solution for fifteen minutes. Afterwards put the clean electrodes out somewhere to dry.

Literature

Band, G. P. H. (2011). Syllabus for the master course Experimentation II: Neuroscientific Research Methods. Cognitive Psychology unit, Leiden University.

fMRI scanner Protocol

Needs to be fleshed out

Input Anna Hafkemeijer/Serge Rombouts

After-care Protocol

Needs to be fleshed out

invasive