IDEA-FAST

Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

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**WP 8 –Data protection ,
ethics and legal challenges**

D8.1: The model informed consent for the FS

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1 Abstract

The Feasibility Study must be based on a standard model informed consent form. That model informed consent form should then be adapted by each participating centre according to its own customs (to which the IRB is used) and be made disease specific. The model is attached here. In order to make the text more readable, the informed consent to participate and the privacy statement following article 13 of the General Data Protection Regulation have been separated. The model is based on the model which had been developed in the IMI Big Data for Better Outcomes (BD4BO) project.

2 Model of Informed Consent

The model informed consent of IMI BD4BO and its DO-IT subproject[1] was adopted to the Feasibility Study (FS) and drafts were discussed in the WP 8 group and the FS group for comments. The Do-IT model had been tested in discussions with data protection authorities, ethicists and members of patient organisations. Some fine tuning was necessary of the base model for the FS. After several rounds of comments, the final documents were established as shown in the Appendix. A range of information including duration, timing, disease etc. will be updated in the form subject to the FS final protocol. These are highlighted within the Model of Informed Consent in the Appendix.

3 Conclusions

It proved to be possible to generate a model informed consent form in relatively short time. Feed-back from the participating centres will be needed to assess whether the model and the centre and disease specific adaptation will also be accepted by the relevant ethics committees. That feed-back is important for the clinical validation study.

[1] https://www.imi.europa.eu/projects-results/cataloque-project-tools

Appendix A – the model informed consent form and the privacy statement

Consent template for IDEA-FAST Feasibility Study
(based on the DO-IT model)

Study information

1. What is this study about?
It is still unclear how we can investigate the impact of sleep problems and fatigue (tiredness) on the quality of life of patients with your condition and its impact on everyday activities (e.g. amount of interactions with friends and family, household, eating habits). Current evaluations rely mainly on subjective patient reports. These are very important but not always accurate or timely, and not good at measuring the fluctuations of the symptoms. The IDEA-FAST project seeks to improve these assessments by using the latest advancements in digital technology, such as wearable devices. This should also give doctors timely reliable, objective data that is very much needed for improving fatigue and sleep problems for patients such as yourself. You can read more about IDEA-FAST at www.ideafast.eu.

But how well the data collected by these devices give timely and accurate data to measure sleep and fatigue? Is using those devices sufficiently patient-friendly to use in their day to day lives? We need to investigate that first. That is done in two steps. In a first study with a limited number of patients we not only test whether certain selected devices send data which measure your ability for daily living correctly, but also how you as patient experience the use of those devices. This study will last 60 days.

Based on the experiences of the first study, there will be a second, larger study where patients will be followed for a longer time period. That study will also investigate how using those devices can be used to assess the patient's daily living conditions and quality of life.

You are now asked to participate in the first study.

2. Do I have to take part?
You have a choice whether or not to participate in this study. Whether you participate or not will not impact your usual care and your relationship with your doctor and nurses.
Please take as much time as needed to decide whether you would like to take part in this study.
If you join the study, you can stop at any time. Stopping will not affect your care. If you choose to stop the study, please let us know as soon as possible.
If you do not join the study, you will continue to receive the usual care for your [Describe condition].

3. What will happen if I join the study?
If you choose to join the study, you will attend at least one scheduled study visit at your hospital. During the study visit you will undergo a detailed assessment. The focus will be on evaluating the presence and severity of sleep problems and fatigue as well as disease activity of the underlying disease of interest. You will then be asked to report sleep problems and fatigue during a period of 42 days (six weeks), using a combination of questionnaires and a simple diary.

During the same period, you will use a combination of digital devices in your own environment. This will include a smartphone that has all the necessary applications for communication with the devices preinstalled, so you do not have to worry about setting it up. You will be trained how to use these technologies during the study visit. Additional training and support will be provided via telephone, email, internet, and written materials according to your preference and needs. Information about how to keep an open communication with the Study Team will be provided, including the opportunity to

return devices to the clinics in case of device issues and technical failures if these cannot be solved on your own or in contact with the Study Team. These devices will collect data on things such as quality of sleep and fatigue. Depending on the nature of the device, use may be continuous for this period or restricted to repeated measures at selected time points. You will also be asked to provide feedback about the experience of using the digital devices. You will be asked to use six different combinations of devices and someone from the Study Team will contact you [in person/by phone/by videoconference] after each device use period to talk about your experience and remind you how to use of the next combination of devices. At the end of the study period, you will be invited to attend an optional "End of Study" visit. At this visit a simple clinical assessment will be carried out, together with a brief interview to understand your overall experience. If you choose to attend this visit, you will also be asked to return the digital devices in person, otherwise you may be asked to return the devices by post.

4. What are the required tests and procedures?

You will be asked to use the digital devices sequentially during the six-week assessment period. You will be asked to wear/use up to four mobile devices (at the same time) that require some daily action from your side (charging/wearing the device/answering questions). A detailed schedule of when to wear the devices will be provided to you during the Study Visit. Moreover, you will be contacted every week by a specially trained research staff, to ask whether any issues occurred. Vice versa, you will be able to contact the research staff during working times whenever you have questions about the use of the devices or other study-related matters. Answers to common questions will also be available on the internet.

In addition, you will be asked to report your experience concerning fatigue and sleep in a diary twice a day. Those are simple questions and will take you or your caregiver about four minutes each time. This information will be collected either electronically (mobile phone using either typing or voice recording, depending on your preference) or using a paper diary. [in case of paper diary and no in-person visits during the device period]: The diary will be sent to the investigating team every 14 days. You will receive a reminder to complete the simple questions on the study smartphone.

Following each device use period, you will be asked to review your experience of using the devices. In addition, you will be asked to complete an interview which will be audio-recorded. Any parts that could identify you will be cut from the recording. You will also be asked about your experiences of managing your condition.

5. More about the devices

In a separate leaflet you can see the devices which will be used during the study with a brief description.

6. What are the risks of joining the study?

We do not perceive there to be any meaningful risks associated with joining this study. The sensors that will be used are CE-certified, non-invasive and operate on very low power.

For the study we collect additional data. When those data leave your hospital, they will be submitted to secure servers hosted by Imperial College London, United Kingdom. Theoretically, there is always a very small risk of a data breach. However, the risk is considerably lowered by following the rules set forth in the General Data Protection Regulation (GDPR). For further information regarding the protection of your data, see the GDPR statement.

7. Are there any other considerations or risks I need to know about?

Wearing the devices might give some discomfort. Filling in the diary and the questionnaires can be time consuming. In addition, it might be stressful getting used to different devices in a relatively short period of time. The study team will help you to get used to the devices and support you in case of troubles or concerns.

8. What are the optional tests and procedures?

If you join the study, you will also be asked whether you want to donate biological samples (urine, blood, stool). The donation of biological samples is optional. Hence, it is not necessary for joining the study to donate the samples as well. The samples are collected for possible future research that may help to further investigate the biology causing sleep problems and fatigue in patients with your condition and are therefore not part of this study. The donation will not involve extra medical procedures. It involves material which is either taken from your routine clinical diagnostic procedures or collected by yourself. You can choose to donate one or more types of the biological samples. If you agree, you may provide your consent by ticking the checkbox in the consent form.

9. What are the possible benefits of taking part?
We do not expect there to be any relevant benefits to alleviate your own ailments. The results of the study will therefore have no direct effect on your personal situation but could bring forth new insights that might greatly benefit all future patients who suffer from (name chronic disease).

10. What happens if something changes while I am in the study, e.g., if new information is found?
Changes may happen in the study that could make you change your mind about continuing to take part. If something changes, we will tell you as soon as possible.
You can choose to leave the study at any time. For more details see section below "What will happen if I want to quit the study?".
The study doctor can also choose to take you out of the study if they believe that it is best for you.

11. What happens if I am harmed or injured during the study?
If there is an emergency, call [applicable emergency number to be inserted] right away or go to [insert applicable reference e.g.: the emergency room] and contact your study doctor as soon as you can.
If you have any other acute medical problem, please contact your study doctor right away, especially if you think this may be related to your participation in the study. They will treat you or contact another doctor.
Though we do not foresee such a scenario, you will be insured during the study for any harm which may result of using the device, whether to you or to the device.

12. What will happen to my data and biosamples gathered in the study?
All data collected for the study (from the devices, from your patient file, the questionnaires) will be centrally assembled. Each participant will get a unique code-number and your name and contact details will not be visible in the central collection of the data. Only members of your treatment team will have access to your contact details.

The central collection is necessary because patients from various hospitals are participating in the study and the study analyses must be made on the whole of the data. The central collection is of course well secured according to the latest standards. There are strict access rules and only researchers of the IDEA-FAST team will have access to those data which are necessary for their specific analyses.

Also, the samples will be separately stored and analysed under your code-number.

You can read more about the data, the samples and your rights to the data in the separate leaflet on data protection.

13. What will happen to the overall results of the study?
We intend to publish the results of the study in scientific journals and conventions. All publications will be shown at the IDEA-FAST website. The results will also be discussed with the patient organisations who are members of the IDEA-FAST project. These results are always fully anonymised meaning that nobody will be able to retrieve your identity from those statistics. Additionally, we use the results of this study to design the larger study.

14. What will happen if I want to quit the study?
You can stop your participation at any time. Stopping however is not the same as a withdrawal of consent for processing personal data. Data that have been collected can still be used. See the separate longer leaflet about your data and samples.

15. Who can answer any questions I may have?
During your scheduled study visit at the recruitment centre, you will be given information on how to contact the study doctor for any questions you may have.

16. Possibility of individual results
We may have to study coded data and biosamples from many people over many years before we can know if the results of this study or additional studies are meaningful.
Therefore, you should not expect to receive individual results from this study or additional research projects. Such data will not be given to your doctor and he or she will not put them in your medical record as they are not individual valid results.
However, there is a small chance that we could one day discover something that might be very important to your health or medical care. If this happens while your data is still coded (i.e. not anonymised -) and we still have the link of your name to the number your data has been assigned, we will use reasonable efforts to inform your study doctor, so that he/ she can discuss further options with you to confirm the findings. In case you do not want to be informed about such findings, you have the possibility to opt out by letting your study doctor know about your preferences.

17. Additional (or future) research
We expect that the data will be of great interest for other research into the disease which you are suffering from or related areas such as sleep, fatigue or quality of life research into chronic diseases. We therefore ask for your separate consent for the additional use of your data for such additional research, other than the present study. You are in no way obliged to consent to additional research if you want to participate in the present study.
You can withdraw that consent for this additional research at any time. Withdrawing consent will not have any negative impact on your usual care. If you decide to withdraw from additional research, this means that data will not be used for such research, unless this information is already included in analyses or used in scientific publications. In that case the data will only be used to prove - in case of doubt - that the claims made in the analyses and publications, were valid.
For more information about the additional use of your data, see the separate leaflet on data protection.
The additional research might take place after the standard retention period of the coded data of 25 years. If you consent to additional research, you can also indicate whether the data may be kept longer than 25 years.

GDPR Statement

1. **Which data and biosamples are collected?**

The study team will collect data from interviews, reported feedback, questionnaires, clinical assessments and the measurements taken from the digital devices.
In addition, if you have given informed consent to donate your biological samples (blood, urine, stool) for biobanking, these biosamples will also be collected and data from those samples may be analysed in future research projects.

2. **What are my data and biosamples needed for?**

Your data is needed in order to find new objective and reliable digital measures for problems with sleep, fatigue or other daily living activities (such as social interactions) or quality of life (such as fatigue) accurately and reliably. This will be of great value in the development of treatments for sleep loss/problems and fatigue.

3. **Who assembles the data?**

Most data are in the first instance collected by your hospital. In legal terms that is the controller of the data. Your data will be given a study number and transferred to the University of Cambridge, United Kingdom and the Imperial College London, United Kingdom where the data will be stored securely under that number to allow further analysis of your data.
Also, some of the device-makers will collect data and send these to Imperial College London (see below). The study team has made an arrangement with the device-makers: any data that the device makers may have will be erased as soon as the data collection has ended, which means as soon as you have completed the study. Hence, after six weeks.

4. **Recipients: Who can access my data?**

The study doctor and the study team have access to your full data. Data will be stripped of your direct identifiers, such as e.g. your name, address and social security number and will be given a study number which is unique for you. These will then be sent to the IDEA-FAST data management platform. The platform will be hosted in secure servers provided by Imperial college London (ICL), United Kingdom. ICL will become the new controller in the sense of the General Data Protection Regulation of the coded data stored on the platform.
The address of ICL is: South Kensington, London SW7 2BU, United Kingdom

5. **What is the legal basis to collect the data?**

When consenting to participate in the study, you also consent to data processing which is necessary for the aims of the study. You also agree that the coded data and tissue samples will be sent to the United Kingdom and remain stored there also if there would not be an agreement between the European Union and the United Kingdom about the adequacy of the data protection in the UK as compared to the EU.

6. **The biosamples**

If you have also consented to the collection and analysis of biosamples, these samples will be stored under your code-number at the Newcastle Academic Health Partner Biobank, based at the Newcastle University, Newcastle upon Tyne, UK. The biobanked samples are intended to be stored for up to 25 years. The biobanked samples will not be used for animal research or for reproductive biology research. At Newcastle Academic Health Partner Biobank the samples will be analysed. Under specific conditions they can also be analysed at other biobanks. The resulting data can be can be used for research combined with the data on the IDEA-FAST data management platform described in point 4, or used for research without using other coded data.

7. Who else may have access to my data and why?

There are strict rules to access data on the IDEA-FAST data management platform. Only researchers which need data for their analyses will be given access and their handling of the data will be monitored. IDEA-FAST endorses the so-called FAIR principles of health sciences. FAIR stands for 'findable, accessible, interoperable and re-usable'. The idea behind FAIR is that all data remains available to replicate the research and that new research can be undertaken on existing data so that participants are not requested to undergo procedures for a new study while such data are already available. FAIR also reduces waste of scarce research funds.
However, IDEA-FAST will only allow research by researchers other than the IDEA-FAST study team:
• If that research is done on the safe IDEA-FAST data management platform;
And:
• If the research question differs from the original research question to which you consented, only if you have also agreed to further research into the disease which you are suffering from or related areas such as sleep, fatigue or quality of life research into chronic diseases.

8. How long will my coded data and biosamples be kept?

Your coded data and biosamples will be kept for a period of 25 years, unless there is a legal requirement for keeping them longer. After that period the coded data will be deleted or anonymised. Biosamples will be destroyed unless you give consent for a longer storage.

9. What are my rights under data protection law?

If you want to know which data concerning you are held at the IDEA-FAST data management platform, please consult your study doctor. However, this will no longer be possible after the study key code has been destroyed. Because of the coding, ICL cannot identify you in the database.
You have the right to withdraw your consent to the processing of your personal data at any given time. When you withdraw your consent for the data processing during the study, you will also be considered to have withdrawn your consent to participate in the study.
After withdrawal of your consent, the data that has already been used for analyses will still be kept. This is necessary to validate the results and assure research integrity. However, the data will not be used for any further analyses.

10. Further information

How your hospital handles personal data is also overseen by the Data Protection Officer (DPO) of your hospital. The DPO can be reached via……..

11. Complaints

In addition to the complaints procedure of your hospital, you can file a complaint at the ….*relevant Data Protection Authority (DPA)* … if you consider that your rights under the data protection legislation have been violated. The address is:
……..