# Effectiveness of Flight Time Limitation (FTL)

## *D2.2 Definition of the Data Collection Process*

MOVE/C2/2016-360
Classification: Restricted

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# Chapter 1: Introduction to the research study

## Main objective and scope of the research study

The European Aviation Safety Agency (EASA) was mandated to perform a continuous review of the effectiveness of the rules concerning flight and duty time limitations and rest requirements contained in Annexes II and III of Commission Regulation (EU) No. 965/2012[1].

The review commenced in 2017 with the commission of a research study.

The research study was broken down into smaller phases; each focused on specific flight duty periods (FDPs). The first and current research phase studied the following two FDPs:

- FDP1: Duties of more than 10 hours at the less favourable time of day.
  This focuses on operations that encroach (fully or partially) any portion of the period between 02:00h and 04:59h; and
- FDP2: Disruptive schedules.
  This focuses on consecutive early duty starts, late duty finishes, night duties, and combinations thereof.

## Scope of the current deliverable

This Deliverable D2.2 (Definition of the Data Collection Process) details the scope and process of the data collection.

For D2.2 the research protocol template from the CCMO (Dutch central committee on research involving human subjects) was used to set up to measurement protocol for the FTL research study. The protocol was reviewed by the Dutch ethics review committee on research involving human subjects (in Dutch the 'Medisch Ethische Toetsing Commissie') at the Amsterdam UMC), reference W17_117.136,

[1] Commission Regulation (EU) No. 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No. 216/2008 of the European Parliament and of the Council.

# Chapter 2: Research protocol

Review of the effectiveness of the EU flight time limitation for aircrew

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# Introduction and rationale

The European Commission (EC) together with EASA has set up a research study to perform a review of the effectiveness of the flight and duty time limitations and rest requirements applicable as of 18 February 2016[2]. The objective is to determine whether these rules provide sufficient protection from potential consequences of aircrew[3] fatigue and, if necessary, to make recommendations for changes to the rules.

This FTL review is being performed by a research consortium with the Netherlands Aerospace Centre NLR, in collaboration with Stockholm University, Finnish Institute of Occupational Health FIOH, German Aerospace Centre DLR, and Jeppesen. The study is financed by the EC.

In order to guarantee that the work performed adheres to the highest scientific standards, a committee of renowned independent scientific experts was set-up by EASA. This group of experts from Europe and the US supports the current research study. In addition, a 'Mirror group' of representatives from the main interested parties – viz. Member State, regulators, airlines and aircrew associations – was set-up by EASA. This group supports the research consortium in setting the definition of the scope and scale of the work to be performed with the goal of guaranteeing its fitness for purpose in effectively mapping aircrew fatigue within the European aviation sector. In particular, the Mirror group acts as liaison between the study team and the aviation community.

## Fatigue as an operational safety risk

Commercial aviation operational demands require 24-hour-a-day activities that can include shift work, night work, irregular and unpredictable work schedules, and time zone changes. Flight operations often are associated with sleep loss and circadian disruption, both of which have the potential to result in harmful effects on operator performance and alertness. While the debilitating effects of sleep loss have been documented for many years[4], more recent research has focused on sleep, circadian rhythms, sleepiness/alertness and the performance decrements associated with operational environments[5].

Also, a considerable amount of research has been carried out on the performance of shift workers[6,7], with emphasis on such issues as the effect of speed and direction of rotation, the number of consecutive nights, and the comparison between 8- and 12-hour shifts[8]. However, it is difficult to apply many of the results directly to transport workers, whose patterns of work tend to be irregular and subject to last-minute changes and unexpected delays. In addition, the long-haul pilot and cabin crew are subject to further disruption from time zone changes and resultant de-synchrony between the timing of the body clock, local light/dark cycle, meal availability and social interaction.

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[2] EASA is mandated to perform a continuous review of the effectiveness of the provisions concerning flight and duty time limitations and rest requirements contained in Annexes II and III of Commission Regulation (EU) No. 965/2012.

[3] Aircrew refers to pilots and cabin crew members.

[4] Pilcher, J. J., & Huffcutt, A. I. (1996). Effects of sleep deprivation on performance: A meta-analysis. *Sleep, 19(4)*, 318-326.

[5] Roach, G. D., Rodgers, M., & Dawson, D. (2002). Circadian adaptation of aircrew to transmeridian flight. *Aviation, Space, and Environmental Medicine, 73*(12), 1153-1160.

[6] Åkerstedt, T. (1998). Shift work and distributed sleep/wakefulness. *Sleep Medicine Reviews, 2*, 117-128.

[7] Folkard, S., & Tucker, P. (2003). Shift work, safety and productivity. *Occupational Medicine, 53*, 95-101.

[8] Knauth, P. (1995). Speed and direction of shift rotation. *Journal of Sleep Research, 4(Suppl. 2)*, 41-46.

Although countermeasures to sleep deprivation such as napping before and during duty can help[9,10], it is likely that some adverse effects will persist. The aviation community has examined the effects of sleep loss and circadian disruption on flight crews by conducting controlled research in laboratory, simulator and field studies[11,12,13,14,15]. These studies have confirmed the presence of fatigue-related performance challenges in flight crew from the sleep loss and circadian disruption. A fall in alertness leads to slowed reaction times and reduced vigilance, poor decision making, and lack of communication. In other words, the factors challenging human physiology can result in performance-impairing fatigue and an increased risk to safety.

The considerable and diverse evidence relating fatigue to safety was reviewed in detail by Williamson et al.[16]. These authors considered the impact of three categories of potential sources of fatigue, namely homeostatic factors (i.e., time since sleep), circadian influences (i.e., time of day) and nature of the task (e.g. duration, workload and monotony) on (i) actual accidents and injuries and (ii) performance decrements that might result in accidents or injuries. The results concerning homeostatic influences were fairly straightforward and consistent: the longer someone had been awake for or the shorter the duration of their sleep period, the higher the risk of accidents and injuries and the greater the performance decrements. Thus, for example, Connor et al.[17] found that after adjusting for demographic variables, drivers who had slept for five hours or less the previous night were 2.7 times more likely to be involved in a car accident than those who had slept for more than five hours. The evidence concerning circadian influences is, however, more complex. It is well established that both subjective ratings of fatigue and objective sleep measures such as sleep latency show marked circadian rhythm effects with a maximum effect occurring between 03:00h and 04:59h. However, reviewing the available evidence Folkard et al.[18] concluded that, after correcting for exposure, accident and injury propensity reaches an earlier maximum at about midnight. Mustard et al.[19] confirmed this earlier than expected risk peak in a recent study of work injury risk by time of day. With regard to performance measures, laboratory studies of circadian rhythms have obtained mixed results with some measures of performance showing a direct circadian component while others would appear to only do so in combination with homeostatic factors.

[9] Åkerstedt, T., & Torsvall, L. (1985). Napping in shift work. *Sleep, 8*, 105-109.
[10] Knauth, P., & Hornberger, S. (2003). Preventive and compensatory measures for shift workers. *Occupational Medicine*, 53, 109-116.
[11] Dinges, D. F., & Kribbs, N. B. Performing while sleepy: effects of experimentally-induced sleepiness. In T. Monk (Ed.), *Sleep, Sleepiness, and Performance*. Chichester, UK: John Wiley and Sons, Ltd; 1991: 98-128.
[12] Cabon, P., et al. (1993). Human vigilance in railway and long-haul flight operation. *Ergonomics, 36*, 1019-1033.
[13] Caldwell, J. A., et al. The effects of ultra-long-range flights on the alertness and performance of aviators (NASA Technical Memorandum 2006-213484), Moffett Field, CA: NASA Ames Research Center.
[14] Gander, P. H., et al. (1998). Flightcrew fatigue V: long-haul air transport operations. *Aviation, Space, and Environmental Medicine, 69(9 Suppl)*, B37-48.
[15] Powell, D., Spencer, M. B., Holland, D., Broadkent, E., & Petrie, K. J. (2007). Pilot fatigue in short-haul operations: effects of number of sectors, duty length, and time of day. *Aviation, Space, and Environmental Medicine, 78*, 698-701.
[16] Williamson, A., Lombardi, D. A., Folkard, S., Stutts, J., Courtney, T. K., & Connor, J.L. (2011). The links between fatigue and safety. *Accident Analysis & Prevention, 43*. 498-515.
[17] Connor, J., Norton, R., Ameratunga, S., Robinson, E., Civil, I., Dunn, R., Bailey, J., & Jackson, R. (2002). Driver sleepiness and the risk of serious injury to car occupants: Population based case control study. *British Medical Journal, 324*, 1125-9.
[18] Folkard, S., Lombardi, D. A., & Spencer, M. B. (2006). Estimating the circadian rhythm in the risk of occupational injuries and “accidents”. *Chronobiology International, 23*, 1181-1192.
[19] Mustard, C. A., Chambers, A., McLeod, C., Bielecky, A., & Smith, P. M. (2013). Work injury risk by time of day in two population-based data sources. *Occupational and Environmental Medicine. 70*, 49–56.

In aviation, the link between fatigue and safety is particularly difficult to establish because of the very low accident rate and the complexity of accident aetiology[20]. In fact, multiple layers of operational defences (task automation, checklists, crew resource management strategies, standard operating procedures, etc.) reduce the probability of having an aviation accident attributable to a single cause (here a decrease in human performance due to fatigue). The use of these strategies could explain the non-linear relationship between safety-related indicators and fatigue-related indicators. In the context of regional flights, Cabon et al.[21] found that crew operating under reduced rest provisions (a minimum of 7 hours 30 minutes instead of the standard rest of 13 hours between shifts), had a decrease in the frequency of flight data monitoring events (of all severity levels) for the duties associated with the highest risk of fatigue. However, the same study found that when the risk of fatigue was elevated, more serious exceedance levels were likely to occur.

## Limiting flight time – the need for research

Traditionally, the aviation industry has taken a regulatory approach to fatigue prevention through the specification of flight and duty time limitations scheme, collectively referred to as flight time limitations (FTLs). This is done by limiting the number of hours aircrew can work and specifying the minimum rest time which is required before commencement of each flight duty period.

Over time, FTLs have evolved, driven by industrial pressures, new scientific data or needs for adaptation to evolving aircraft capabilities. Nowadays, there are differences among FTLs formulations in different parts of the world, influencing crew productivity and crew alertness, and, ultimately, airline competitiveness. In view of the over-arching importance of the issue, there has been considerable research effort devoted in recent years on increasing our scientific knowledge and information in the areas of fatigue and alertness. The availability of such new research on sleep and work-related fatigue makes it ever more relevant to compare prevailing regulations with the new insights.

The Regulation (EC) No. 1899/2006 on the harmonisation of the technical requirements and administrative procedures in the field of civil aviation required the European Aviation Safety Agency (EASA) to conduct a scientific and medical review of Subpart Q of Annex III of the Regulation. This was performed in the course of 2008 with the relevant results accessible through the report 'Scientific and Medical Evaluation of Flight Time Limitations'[22].

This review report (also referred to as the Moebus review) revealed that field studies of single-sector two-crew operations had shown that some crews were having difficulty remaining awake during overnight duties of 11 hours or more[23,24]. Furthermore, the review showed that the development of cumulative fatigue tends to increase during

[20] Amalberti, R. (2001). The paradoxes of almost totally safe transportation systems. *Safety Science, 37*, 109-126.
[21] Cabon, P., Deharvengt, S., Grau, J. Y., Maille, N., Berechet, I., & Mollard, R. (2012). Research and guidelines for implementing Fatigue Risk Management Systems for the French regional airlines. *Accident Analysis & Prevention, 45(Suppl)*, 41-44.
[22] Moebus Aviation Final Report "Scientific and Medical Evaluation of Flight Time Limitations" (TS.EASA.2007.OP.08, Final Report, 30 Sept. 2008).
[23] Samel, A., Wegmann, H. M., Vejoda, M., Drescher, E. E. J., Gundel, A., Manzey, D., & Wenzel, J. (1997). Two-crew operations: Stress and fatigue during long-haul night flights. *Aviation, Space, and Environmental Medicine, 68(8)*, 679-687.
[24] Spencer, M. B., & Robertson, K. A. (1999). The Haj operation: alertness of aircrew on return flight between Indonesia and Saudi Arabia. DERA Report No. DERA/CHS/PPD/CR980207/1.0, Farnborough, UK.

consecutive periods of duty, especially for long duties or when early starts, late finishes or overnight duties are involved that disrupt the normal pattern of sleep[25,26].

The evaluation of scientific studies in the field of fatigue management existing at the time of the Moebus review revealed the need to conduct additional research to assess the quality of the new EU crew member fatigue management framework.

## Objectives

The purpose of the FTL measurement campaign is to collect aircrew data on fatigue, alertness, mental effort and sleep. The fatigue data is used to detect the prevalence of high levels of fatigue in two specific envelopes of aircrew duty periods within Regulation No. 965/2012. The data on alertness, mental effort and sleep are not directly considered in the primary and secondary objectives. However, they will be addressed in supplementary analyses of the data.

The two FDPs[27] that are the specific focus of this study are:

- FDP1: Duties of more than 10 hours at the less favourable time of the day.
  This refers to operations that encroach (part of) the night (the period between 02:00h and 04:59h); and
- FDP2: Disruptive schedules.
  This refers to repetitive early starts, late finishes, night duties, and combinations thereof.

For the FTL research study, a high level of fatigue is defined by scores of the Karolinska Sleepiness Scale (KSS) > 6 and Samn-Perelli rating scale (SP) > 5 for a considerable portion of flight.

KSS is a frequently used measure to assess sleepiness on a 9-point scale. It has been extensively validated in shift workers, drivers and aircrew[28,29,30]. Level 7 ('Sleepy, but no difficulty remaining awake') indicates the start of electroencephalographic and electrooculographic changes, representing sleepiness; and level 8 ('Sleepy, some effort to keep awake') to 9 ('Very sleepy, fighting sleep, an effort to keep awake') is associated with high probability of line crossings on real roads and accidents in simulators.

SP is another commonly used fatigue rating scale. SP is a 7-point scale. Level 6 is defined as 'Extremely tired, very difficult to concentrate'; and level 7 as 'Completely exhausted, unable to function effectively'. These rating criteria were based on operational experience in the specific context of military airlift operations[31]. We are not aware of any attempt to quantify the safety risk represented by different scores in other operational settings.

[25] Spencer, M. B., & Robertson, K. A. (2000). A diary study of aircrew fatigue in short-haul multi-sector operations. DERA Report No. DERA/CHS/PPD/CR00394, Farnborough, UK.
[26] Spencer, M. B., & Robertson, K. A. (2002). Aircrew alertness during short-haul operations, including the impact of early starts. QinetiQ Report No. QINETIQ/CHS/PPD/CRO10406/1.0, Farnborough, UK.
[27] This concerns non-augmented crews only.
[28] Sagaspe, P., et al. (2008). Extended driving impairs nocturnal driving performances. *PLoS ONE, 3*(10), e3493.
[29] Åkerstedt, T., & Gillberg, M. (1990). Subjective and objective sleepiness in the active individual. *International Journal of Neuroscience, 52*, 29-37.
[30] Åkerstedt, T., & Anund, A., Axelsson, J., & Kecklund, G. (2014). Subjective sleepiness is a sensitive indicator of insufficient sleep and impaired waking function. *Journal of Sleep Research, 23*, 240-252.
[31] Samn, S. W., & Perelli, L. P. (1982). Estimating aircrew fatigue: a technique with implications to airlift operations. USAF School of Aerospace Medicine Technical Report No. SAM-TR-82-21.

## FDP1: Duties of more than 10 hours at the less favourable time of the day

### Primary objective FDP1

To assess the prevalence of high levels of fatigue during duties of more than 10 hours at the less favourable time of the day (between 02:00h and 04:59h).

Main (primary) hypothesis FDP1
$H_0$ = High KSS and SP scores do not occur in flight duties longer than 10 hours that take place between 02:00h and 04:59h.
$H_1$ = High KSS and SP scores occur in flight duties longer than 10 hours that take place between 02:00h and 04:59h.

### Secondary objective FDP1

To further explore the relation between duties encroaching (part of) the period between 02:00h and 04:59h and scores on the KSS and SP.

Secondary hypothesis FDP1
$H_0$ = There is no relation between mean KSS and SP scores, total duty duration and duty time between 02:00h and 04:59h.
$H_1$ = Mean KSS and SP scores increase when total duty duration and duty time between 02:00h and 04:59h increases.

## FDP2: Disruptive schedules

### Primary objective FDP2

To assess the prevalence of high levels of fatigue during (consecutive) disruptive flight schedules.

Main (primary) hypothesis FDP2
$H_0$ = High KSS and SP scores do not occur in (consecutive) disruptive flight duties, irrespective of number of type: early start, late finish, night, or mix.
$H_1$ = High KSS and SP scores occur in (consecutive) disruptive flight duties irrespective of number of type: early start, late finish, night, or mix.

### Secondary objective FDP2

To further explore the relation between consecutive disruptive flight schedules and scores on the KSS and SP.

Secondary hypothesis FDP2
$H_0$ = There is no relation between the mean KSS and SP scores and the number of consecutive disruptive schedules flown.
$H_1$ = Mean KSS and SP scores increase as a function of the number of consecutive disruptive schedules flown.

Early start, late finishes, night duties and mixed types will be considered separately here.

# Study design

The study is designed to collect crew data on fatigue, alertness, mental effort and sleep in an operational environment, namely in flight operations of two specific FDPs.

The duration of the data collection campaign for the participating aircrew members is a period of 14 consecutive days. Each day the participating aircrew members will be asked – during normal flight duties and during days off – to regularly fill in rating scales on a smartphone or tablet app, and to keep a sleep log, and to perform a reaction time test. Participants will also be asked to wear an actigraph.

Duties that do not fall within the definitions of FDP1 and FDP2 will be recorded in the two-week period of measuring. These duties will be used for control purposes.

# Study population

## Population (base)

The population base concerns all aircrew working for European CAT operators that have to follow the flight and duty time limitations and rest requirements applicable as of 18 February 2016[32].

The size of this population base has been estimated based on numbers received from EASA, completed (and verified) by an internet search and checks at random airlines operators. The estimate was based on:

- The fleet size of all airline operators within the population base; and
- Estimates of required aircrew sizes of all airline operators for each type of aircraft based on the type of operations (short-, medium-, and long-haul, regional, and sole cargo flights[33]).

This resulted in the following estimate of the population base per European region[34]:

| | ***Pilots*** | ***Cabin crew*** | ***Total aircrew*** |
|---|---|---|---|
| | *No.* | *No.* | *No.* |
| ***North Europe*** | 6,530 | 7,678 | 14,208 |
| ***West Europe*** | 35,035 | 52,522 | 87,557 |
| ***South Europe*** | 14,710 | 22,185 | 36,895 |
| ***East Europe*** | 3,930 | 5,171 | 9,266 |
| ***Europe*** | 41,430 | 87,556 | **147,926** |

## Selecting a balanced set of EU air operators and operations

An overview of European CAT operators classified by Member State and sub-classified by type of operation was assembled[35]. This population was used as reference set for purposes of performing the subsequent data collection. We defined the following criteria to narrow the EU aviation ensemble that was determined:

- Volume of air operations (as a function of the number of aircraft), as this was considered a key determinant of operators' exposure to fatigue;

[32] The provisions concerning flight and duty time limitations and rest requirements contained in Annexes II and III of Commission Regulation (EU) No. 965/2012.
[33] As defined in D1 Addendum.
[34] Note that in D1 Addendum the four European regions are defined.
[35] Note that in D1 Addendum this overview of operators is illustrated.

- The extent to which operators used deviations or derogations from the EU FTL Regulation. Airline operators that use such flexibility were excluded; and
- The type of FDPs performed by the operators. The operators should operate (at least) one of the two earmarked duty periods for inclusion to be possible.

Application of these criteria resulted in a set of candidate air operators. From this set of operators aircrew participants will be recruited for the study.

### Inclusion criteria

To be eligible to participate in this study, participants had to meet the following criteria:

- Be a pilot or cabin crew member working for one of the EU CAT operators taking part in the research;
- Operate (non-augmented) one or both of the two earmarked duty periods:
  - FDP1: Duties of more than 10 hours at the less favourable time of the day; and
  - FDP2: Disruptive schedules.

### Exclusion criteria

This single exclusion criterion is applied to this study:

- For aircrew to participate in the study, they need to have available an iPod, iPhone Touch or iPad as the CrewAlert app that is used for data collection only runs on iOS devices.

## Sample size estimation

The sample sizes required refer to the number of participants needed for the study to provide reliable answers to the research questions. Each participant will contribute to a dataset for 14 consecutive days. It is assumed that within these 14 days at least one flight will answer to the conditions defined by the single targeted FDP; thus resulting in one valid measurement within the 14 day-period per participant. The remaining flights will used for reference/control.

### FDP1: Duties of more than 10 hours at the less favourable time of the day

The primary objective for FDP1 is to assess the prevalence of high levels of fatigue during duties of more than 10 hours at the less favourable time of the day. This will be assessed by calculating the confidence interval (CI) of the probability that the KSS is scored 7, 8 or 9 or the SP is scored 6 or 7 at top of descent (TOD) when flying FDP1. This interval will be compared with zero.

The required sample size for comparing a proportion to zero is an estimate and is largely dependent on the expected effect size. Sallinen et al. (2017) [36] is one of the few studies that report the percentage of night flights where a score of 8 or 9 was measured on the KSS. Therefore, these percentages were used as an input for estimating the expected effect sizes.

The sample size to test the primary hypothesis should be 34 pilots and 34 cabin crew members, totalling 68 participants. This estimation[37] is based on the following parameters:

[36] Sallinen, M., Sihvolaa, M., Puttonena, S., Ketolac, K., Tuoric, A., Härmäa, M., Kecklundd, G., & Åkerstedt, T. (2017). Sleep, alertness and alertness management among commercial airline pilots on short-haul and long-haul flights. *Accident Analysis & Prevention*, *98*, 320-329.

[37] Moore, D. S., & McCabe, G. P. *Introduction to the practice of statistics*, USA: W. H. Freeman and Company, 2006.

- Confidence level > 0.95;
- Power = 1.0;
- $P_{expected}$ (KSS = 8 or 9 for FDP1) = 0.12;
- Margin of error = 0.11.

The secondary hypothesis uses a multiple regression analysis with two independent variables. The expected effect size is unknown; therefore a medium effect is anticipated. The sample size estimation results in a sample of 67 pilots and 67 cabin crew members, totalling 134 participants. This calculation[38] is based on the following parameters:

- Confidence level > 0.95;
- Power > 0.8;
- $P_{expected}$ = 0.15; and
- Number of predictors = 2.

### FDP2: Disruptive schedules

The primary objective for disruptive schedules is also to assess the prevalence of high levels of fatigue. Therefore, as with FDP1, a comparison of proportions will be performed. However, information on the expected effect size on the KSS or SP for this type of schedule was not found in the available literature. Therefore, the sample size of the FDP1 of 68 will be applied for FDP2 as well.

The secondary hypothesis requires the same calculation as for the secondary hypothesis of FDP1, but with only one predictor. This adds up to a required sample size of 54 per disruptive schedule type, leading to a total sample size of 216 pilots and 216 cabin crew members, totalling 432 participants.

### Resulting total sample size estimation

Some gathered data points may not be useable for various reasons, such as not following protocol, withdrawal from the study, errors in gathering data, or not flying one of the targeted FDPs due to a roster change. For this an extra buffer of 10% will be used.

For FDP1 the total required number of participants becomes 134 + 10% = 148 participants (i.e., 74 pilots and 74 cabin crew members).

For FDP2 the total required number of participants becomes 432 + 10% = 476 participants (i.e., 238 pilots and 238 cabin crew members).

These sample size calculations provide an estimation of the expected proportion of aircrew who will report high scores on the KSS and SP. However, it does not inform us about the required sample size based on the subjective views on this study. This so-called face validity will also be taken into account in the sample size estimation for the FTL study. That is, the recruitment of participants will not necessarily stop when the 148 for FDP1 and 476 for FDP2 measurements have been obtained. It will rather continue until a representative distribution of airlines across Europe and with respect to the type of operations (short-, medium-, and long-haul, regional, and sole cargo flights) is reached.

[38] Http://www.danielsoper.com/statcalc/calculator.aspx?id=1

# Study methods

## Measuring fatigue

Field studies often use sleepiness or fatigue ratings. One frequently used measure is the KSS, which measures sleepiness on a 9-point scale from 'extremely alert' to 'very sleepy, great effort to keep awake, fighting sleep'. It has been validated[39] and is used to measure subjective sleepiness in both laboratory and field studies[40,41]. Another relevant and frequently used rating scale is the SP. SP is a 7-point scale with possible scores ranging from 1 ('fully alert, wide awake') to 7 ('completely exhausted, unable to function effectively'). The SP crew status check was developed specifically for use with flight crew[42,43]. It has been used in studies focused on sleep loss, fatigue, and performance of flight crew[44], as well as in laboratory studies[45]. Both the KSS and SP have the advantage of being easy to use in an operational environment. Both rating scales are incorporated in the CrewAlert app and will be used as a measure in the data collection campaign.

## Measuring performance

The psychomotor vigilance task (PVT) is a widely used and validated performance measure[46,47]. The PVT is a sustained-attention, reaction-timed task that measures the speed with which subjects respond to a visual stimulus. The 5-minute version incorporated in the CrewAlert app will be used in this study.

## Measuring sleep

Actigraphy is an objective, non-intrusive and valid measure of sleep quantity and timing. Total sleep time measured by actigraphy is highly correlated with that measured by polysomnography among flight crews while in flight and during layover[48]. The Philips Respironics Actiwatch 2 that was validated against polysomnography[49,50] will be used in this study.

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[39] Kaida, K., Takahashi, M., Åkerstedt, T., Nakata, A., Otsuka, Y., et al. (2006). Validation of the Karolinska sleepiness scale against performance and EEG variables. *Clinical Neurophysiology*, *117(7)*, 1574-1581.
[40] Gillberg, M., Kecklund, G., & Åkerstedt, T. (1994). Relations between performance and subjective ratings of sleepiness during a night awake. *Sleep*, *17(3)*, 236-241.
[41] Härmä, M., Sallinen, M., Ranta, R., Mutanen, P., & Muller, K. (2002). The effect of an irregular shift system on sleepiness at work in train drivers and railway traffic controllers. *Journal of Sleep Research*, *11(2)*, 141-151.
[42] Samn, S. W., & Perelli, L. P. (1982). Estimating aircrew fatigue: a technique with implications to airlift operations. USAF School of Aerospace Medicine Technical Report No. SAM-TR-82-21.
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A sleep diary or sleep log is a record of an individual's sleeping and waking times. The sleep logging incorporated in the CrewAlert app will be used.

## Measuring mental effort

Mental effort will be considered in the study by means of a subjective rating scale; that is, the level of mental effort experienced by the participant in the particular duty period will be rated by moving a slide bar. The bar runs from 'almost no effort' to 'extreme effort' and is based on the rating scale mental effort (RSME)[51].

## Measuring work-related inputs

We will ask aircrew to fill in the following work-related information on the CrewAlert app:

- Duty period: This includes the departure and arrival times at airports;
- Number of legs per duty period;
- Time zone shift: This concerns reporting the time zone at duty start and end;
- Briefing and debriefing duration;
- In-flight sleep duration: This concerns reporting the duration of the obtaining sleep of the crew during flight duty;
- Hassle factors: This concerns selecting daily crew hassles from a pre-defined list. We based this list on the list used in the Vejvoda et al. research[52] on pilots, and completed this with items for cabin crew. The list of hassle factors incorporated in the CrewAlert app is:
    - No break;
    - Bad weather;
    - Demanding airport;
    - High density airspace;
    - Sluggish ground handling;
    - Tight crew rotation;
    - Technical defect;
    - Duty change on short notice;
    - Hotel (noisy/low quality);
    - Difficult passengers;
    - Low quality food;
    - Long travel from airport to hotel;
    - Short turn-around;
    - Delay/time pressure;
    - Emergency;
    - Critical fuel status;
    - Abnormal procedures;
    - Waiting times between flights;
    - Difficulty getting through security;
    - Insufficient baggage handling; and
    - Other.

If needed, for example in case a participant gets sick or reports in 'not fit to fly', participants have the possibility of filling in notes for each duty period.

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## Measuring demographics

Aircrew will be asked to provide the following demographic information: gender, age, height, weight, position, habitual sleep length, home base, typical commute time at home base, and diurnal type/chronotype (eveningness vs morningness). The CrewAlert app will be used to collect this information.

## Study procedures

This study will involve participation in a measurement campaign of 14 consecutive days. Each day the participant will be asked – during normal flight and during days off duties – to regularly fill in different rating scales, to continuously wear an actigraph (although not all participants will be asked to wear one), to keep a sleep log, and to perform a reaction time test (the latter only applies for pilots). In total this will take about 15 to 20 minutes per day.

During a typical flight duty day in the measurement campaign the participant will be asked to do the following:

- After the participant wakes up:
  - Fill in the sleep log on the CrewAlert app on their smartphone or tablet;
  - Rate the KSS and SP on the app; and
  - Complete the PVT on the app.
- When the participant starts his/her FDP:
  - Rate the KSS and SP 15 minutes prior the top of descent of each sector. In case of long-haul flights also rate KSS and SP during cruise;
  - Complete the PVT 15 minutes prior the top of descent of the final sector of that day;
  - Press the button on the actigraph, each time the participant is planning to take a nap; and
  - Fill in the sleep log on the app after taking a nap.
- When the participant ends the FDP:
  - Rate mental effort with the slide bar;
  - Fill in hassle factors;
  - Fill in worked flight schedule;
  - Press the button on the actigraph, indicating the time that the participant is going to sleep; and
  - Fill in the sleep log.

Before the measurement campaign starts, the participant will be instructed by the airline coordinator (supported by the investigator) on what is expected throughout the 14 days. The participant will be trained on how to download, use and fill in the required data collection app on their smartphone or tablet. The 14 days of data collection will start with two days off. The first of these two days will be used for familiarization with filling in the CrewAlert app; and the second day to gather baseline measures of KSS, SP and PVT. During off-duty periods (including the first two days), besides (if) wearing the actigraph, participants will be asked to rate KSS and SP and to perform the PVT three times a day; that is, in the morning, in the afternoon and in the evening.

Participants will be asked to try and settle down a few minutes before completing the KSS, SP and PVT. For completing the PVT they will be asked – if possible – to go somewhere quiet and where they will not get disturbed (e.g. in the car just before duty begins).

Every time before the PVT is administered, the participant will be asked to close all other apps on their device.

Note that only the pilots will be asked to complete the PVT. Completion of the PVT in a busy cabin is expected to have detrimental effects on the output and will therefore not be considered in this study. This is confirmed by the recent study from Van den Berg et al.[53] who questioned the use of PVT in cabin crews without having a proper timing and/or location for completing the PVT. In their study it resulted in a large variability of the subsequent test results.

Note that only a subgroup of participants within each airline will be asked to wear the actigraph. In each selected airline a subgroup of about 20 participants will wear one. This is due to the availability of the actigraphs and logistical constraints within the study.

### Withdrawal of individual participants

Participants can leave the study at any time for any reason, if they wish to do so, without any consequences.

### Replacement of individual participants after withdrawal

Not applicable.

### Premature termination of the study

It is up to the participant to decide whether or not to participate in the study. Participation is entirely voluntary.

If the participant does participate in the study, he/she can always change his/her mind and decide to stop at any time during the study. The data collected until that time may still be used for the study, unless the participant asks the investigator not to.

If there is any new information about the study that is important for the participant, the investigator will let the participant know. The participant will then be asked whether he/she still want to continue participation.

To be clear: participation in the study stops when:
- The participant chooses to stop; or
- The end of the data collection period has been reached after 14 days.

## Safety reporting

### Temporary halt for reasons of participant safety

The sponsor and/or investigator will suspend the study if there is sufficient ground that continuation of the study will jeopardise participant health or safety. The investigator will notify the accredited ethics review committee without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited ethics review committee. The investigator will take care that all participants are kept informed.

[53] Berg, M. J. van den, Signal T. L., Mulrine, H. M., Smith, A. A. T., Gander, P. H., & Serfontein, W. (2015). Monitoring and managing cabin crew sleep and fatigue during an ultra-long range trip. *Aerospace Medicine and Human Performance*, *86(8)*, 705-713.

# Statistical analysis

The study parameters will be analysed using the Statistical Package for the Social Sciences (SPSS). See the table in the Appendix.

Missing data will be coded 9999 to indicate that the data is missing. The complete dataset will remain intact for analyses for which the missing data is not essential. If all KSS TOD and SP TOD recordings are missing for a participant, this participant dataset will be removed since these parameters are essential for the analysis.

## FDP1: Duties of more than 10 hours at the less favourable time of the day

Main (primary) hypothesis FDP1

$H_0$ = High KSS and SP scores do not occur in flight duties longer than 10 hours that take place between 02:00h and 04:59h.

$H_1$ = High KSS and SP scores occur in flight duties longer than 10 hours that take place between 02:00h and 04:59h.

This hypothesis will be assessed by calculating the CI of the probability that the KSS is scored 7, 8 or 9 or the SP is scored 6 or 7 at TOD when flying FDP1. This interval will be compared with zero. When the CIs does not include zero, high levels of fatigue may occur.

Required parameters:

- KSS and SP scores TOD for the target flight (dependent variable). For this test the KSS scores will be transformed to 'Yes' (7, 8 or 9) or 'No' (1 - 6) and the SP scores to 'Yes' (6 or 7) or 'No' (1 - 5).

Assumptions:

- The dependent variable should be measured on a nominal scale. This assumption is met.

Secondary hypothesis FDP1

$H_0$ = There is no relation between mean KSS and SP scores, total duty duration and duty time between 02:00h and 04:59h.

$H_1$ = Mean KSS and SP scores increase when total duty duration and duty time between 02:00h and 04:59h increases.

This hypothesis will be tested using a multiple regression analysis.

The required parameters are:

- KSS and SP scores TOD (dependent variable);
- Total duty duration; and
- The duty time between 02:00h and 04:59h.

The assumptions for multiple regression analysis are:

- The dependent variable should be on a ratio scale. The scale is ordinal, but it is common practice to calculate a mean score for the KSS and SP (e.g. Eriksen, Åkerstedt, & Nilsson[54]). Therefore, we will approach this variable as being on a ratio scale;

[54] Eriksen, C. A., & Åkerstedt, T. (2006). Aircrew fatigue in trans-Atlantic morning and evening flights. *Chronobiology International, 23(4)*, 843-858.

- The independent variables should be continuous or categorical. This assumption is met;
- The observations should be independent. This assumption is not met, but since the dataset is large, the observations may be independent enough. This will be tested using the Durbin-Watson statistic;
- There should be a linear relationship between the dependent variable and each of the independent variables. This assumption will be checked using a scatterplot;
- The data needs to show homoscedasticity. This is tested with Levene's test for equality of variance; and
- The data should contain no significant outliers and the residuals need to be approximately normally distributed. This will be checked in SPSS.

## FDP2: Disruptive schedules

Main (primary) hypothesis FDP2

$H_0$ = High KSS and SP scores do not occur in (consecutive) disruptive flight duties, irrespective of number of type: early start, late finish, night, or mix.
$H_1$ = High KSS and SP scores occur in (consecutive) disruptive flight duties irrespective of number of type: early start, late finish, night, or mix.

This hypothesis will be assessed by calculating the CI of the probability that the KSS is scored 7, 8 or 9 or the SP is scored 6 or 7 at TOD when flying FDP2. This interval will be compared with zero. When the CIs does not include zero, high levels of fatigue occur.

Required parameters:

- KSS and SP scores TOD for the target flight (dependent variable). For this test the KSS scores will be transformed to 'Yes' (7, 8 or 9) or 'No' (1 - 6) and the SP scores to 'Yes' (6 or 7) or 'No' (1 - 5).

Assumptions:

- The variables should be measured on a nominal scale. This assumption is met.

Secondary hypothesis FDP2

$H_0$ = There is no relation between the mean KSS and SP scores and the number of consecutive disruptive schedules flown.
$H_1$ = Mean KSS and SP scores increase as a function of the number of consecutive disruptive schedules flown.

These hypotheses will be tested using a regression analysis and will be considered for each type of disruptive duty (i.e., early start, late finish, night or mixed).

The required parameters are:

- KSS and SP scores TOD (dependent variable); and
- Number of repetitions of the duty type.

The assumptions for regression analysis are:

- The dependent variable should be on a ratio scale. The scale is ordinal, but it is common practice to calculate a mean score for the KSS or SP (e.g. Eriksen, Åkerstedt, & Nilsson[55]). Therefore, we will approach this variable as being on a ratio scale;

[55] Eriksen, C. A., & Åkerstedt, T. (2006). Aircrew fatigue in trans-Atlantic morning and evening flights. *Chronobiology International, 23(4)*, 843-858.

- The independent variable should be continuous or categorical. This assumption is met;
- The observations should be independent. This assumption is met;
- There should be a linear relationship between the dependent variable and the independent variables. This assumption will be checked using a scatterplot; and
- The data needs to show homoscedasticity. This is tested with Levene's test for equality of variance; and
- The data should contain no significant outliers and the residuals need to be approximately normally distributed. This will be checked in SPSS.

# Ethical considerations

## Regulation statement

The study will be conducted in accordance with the principles of the Declaration of Helsinki (seventh revision) and in accordance with the medical research involving human subjects act (*in Dutch the 'Medisch Ethische Toetsing Commissie'; WMO*).

## Recruitment and consent

Participants will be recruited by a study coordinator within the involved airlines (e.g. working for the Health and Safety departments). Recruitment will be done via internal mailings and/or briefings. The study coordinator will be informed about the study details through a participant information sheet and by the investigator. This coordinator will inform the participants (i.e., aircrew) and written informed consent will be obtained. The investigator will be available for detailed questions at all times. Participants will be given one week to consider their decision.

It is important to ensure that participation is totally voluntary. It is the individual's choice whether to participate or not. The choice that they make will have no bearing on their job or on any work-related evaluations or reports. They may change their minds later and stop participating even if they agreed earlier.

## Benefits and risks assessment, group relatedness

It is important that the participant properly weighs up the possible benefits and disadvantages before deciding to join.

The participant will not personally benefit from participation in this study. Participation will contribute to answering the question whether the current fatigue management measures are consistent with the delivery of the required levels of safety for commercial aviation.

Personalised feedback based on the data gathered will not be provided by the study team.

The burden for participating in the study is considered minor. Participants are asked to complete measures such as rating scales and performing the 5-minute reaction time test. Per day this will take the participant about 15 to 20 minutes. We ask the participant to keep this up for a total period of 14 consecutive days.

The in-flight measurements will be carried out so that it will under no circumstances interfere with the flying task. The exact moment of the measurement (i.e., 15 minutes prior to top of descent and in case of long-haul flight also during cruise) is determined based on common practices in this type of fatigue measurement campaign. The protocol has been reviewed and approved by both the Scientific Committee and the Mirror Group in which scientific and operational aviation experts are seated.

We ask (a subgroup of) participants to wear an actigraph (watch) for a period of 14 days, so day and night. This may result in some discomfort.

Participation in the study may lead to incidental findings about your sleeping behaviour. Based on actigraph readings (so, only for the subgroup), it is possible to detect sleeping behaviour outside normal values. Although the analysis of the data is not focused on such detections, and therefore changes are very low, it is still possible that we come across these deviations in the dataset. In the unlikely scenario that indications of a possible sleep disorder are found, participants will be made aware and encouraged to seek medical advice and assistance if necessary.

### Compensation for injury

There is no foreseen specific risk of injury for participants in this study. Therefore dispensation was obtained from the statutory obligation to provide additional insurance.

### Incentives

Participants will not be paid for their participation in this study.

However, participants have the chance of winning a prize (gadget of about 150€). A raffle will be run among the 25% of participants within each participating operator airline that uploaded the most valuable data. 'Valuable' will be a weighted sum of number of days covered, number of assessments and the coverage of sleep/wake logs registering actual sleep.

## Administrative aspects, monitoring and publication

### Handling and storage of data and documents

Data of participants will be handled confidentially and anonymously. A participant identification code is used to link the data to the participant. A unique code is generated for each individual and is not based on the participant's initials and birth-date. The principal investigator safeguards the key to the code. The handling of personal data will comply with the Dutch Personal Data Protection act (*in Dutch: wet bescherming persoonsgegevens, WBP*).

The participant data collected through the application (tablet or smartphone) is transferred securely to the repository over an encrypted connection. Participant data (coded/de-identified) is stored in a password-protected central database repository that can be accessed by project members only.

### Monitoring and quality assurance

An ethics and security manager (ESM) is appointed within the study in order to ensure the scientific and technical progress of the study meets ethical and security approval. More specifically the ESM:

- Monitors the ethical and security activities of the project;
- Reviews potential ethical and security issues which arise as data is being collected;
- Makes sure that agreements on the handling of data will be produced and followed;

- Defines the procedures that will be used for participant recruitment (e.g. the process of recruitment, inclusion/exclusion criteria, risks and benefits for the participants); and
- Assesses the whole data collection activity, specifically on any potential effects that may impact the quality of the data collected.

The ESM is Dr Daniel Aeschbach (German Aerospace Centre DLR). The ESM will execute ad hoc and scheduled (quarterly) checks on if and how these procedures are adhered.

## Public disclosure and publication policy

The final report of the FTL research study will be a public report. There is no prearranged policy with the sponsor about scientific publication. However in general we prefer to publish in an open access journal. The final report and possible other publications of the research will not reveal the identity of the participants and involved operator airlines.

# References

Below all key references published in peer reviews journals that are relevant for the study and are discussed in the protocol (not all) are listed. The list of references is the result of a literature study on the state of the art regarding comparable fatigue measurement campaigns in an operational air transport setting[56].

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[56] Check D1 (Definition of the Baseline) of the FTL study for this state of the art overview.

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# List of abbreviations and relevant definitions

| ***Abbreviations and relevant definitions*** | ***Description*** |
|---|---|
| ABR | ABR form, General Assessment and Registration form, is the application form that is required for submission to the accredited Ethics Committee (*in Dutch: Algemene Beoordeling en Registratie*) |
| ANOVA | Analysis of Variance |
| AOC | Air Operator Certificate |
| AMC | Academic Medical Centre |
| BAM | Boeing Alertness Model |
| CAT | Commercial Air Transport |
| CCMO | Central Committee on Research Involving Human Subjects (*in Dutch: Centrale Commissie Mensgebonden Onderzoek*) |
| CI | Confidence Interval |
| D | Deliverable |
| EASA | European Aviation Safety Agency |
| EC | European Commission |
| EEG | Electroencephalography |
| EU | European Union |
| ESM | Ethics and Security Manager |
| FAST | Fatigue Avoidance Scheduling Tool |
| FDP | Flight Duty Period |
| FRM | Fatigue Risk Management |
| FRMS | Fatigue Risk Management System |
| FTL | Flight Time Limitation |
| KSS | Karolinska Sleepiness Scale |
| METC | Medical Research Ethics Committee (i*n Dutch: Medisch Ethische Toetsing Commissie*) |
| NASA | National Aeronautics and Space Administration |
| NASA TLX | NASA Task Load Index |
| PVT | Psychomotor Vigilance Task |
| SAFTE | Sleep, Activity, Fatigue, and Task Effectiveness |
| SP | Samn-Perelli |
| Sponsor | The sponsor is the party that commissions the organisation or performance of the research. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party |
| SPSS | Statistical Package for the Social Sciences |
| TOD | Top Of Descent |
| WBP | Personal Data Protection act (*in Dutch: Wet Bescherming Persoonsgevens*) |
| WMO | Medical Research Involving Human Subjects act (*in Dutch: Wet Medisch-wetenschappelijk Onderzoek met mensen*) |
| WOCL | Window Of Circadian Low |

# Appendix 1: Participant information sheet

**Review of the effectiveness of the EU flight time limitation regulations for aircrew**

Dear Sir/Madam,

You are asked to take part in a research study. Participation is entirely voluntary and requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about the purpose of the study and what it involves. Please read this information carefully and ask the investigator for an explanation if you have any questions. You can also ask the independent expert, who is mentioned at the end of this document, for additional information. Please take all the time you need to reflect on whether you want to participate or not.

**General information**

The European Commission (EC) together with European Aviation Safety Agency (EASA) has set up a research study to perform a review of the effectiveness of the flight and duty time limitations and rest requirements applicable as of 18 February 2016[57]. The objective is to determine whether these rules provide sufficient protection from potential consequences of aircrew fatigue and, if necessary, to make recommendations for changes to the rules.

This review of the flight time limitations (FTL) is being performed by the Netherlands Aerospace Centre NLR, in collaboration with Stockholm University, Finnish Institute of Occupational Health FIOH, German Aerospace Centre DLR, and Jeppesen. The EC is paying for the costs of this study.

In order to guarantee that the work performed adheres to the highest scientific standards, a committee of renowned independent scientific experts is set-up by EASA. This group of experts from Europe and the US supports the current research study. In addition, a 'Mirror Group' of representatives from the main interested parties – viz. Member State, regulators, airlines and aircrew associations – is set-up by EASA. This group supports the study team in oversighting the definition of the scope and scale of the work to be performed with the goal of guaranteeing its fitness for purpose in effectively picturing aircrew fatigue within the European aviation sector. The Mirror Group also expressed their support in the current research study.

This study has been reviewed by the Dutch ethics review committee on research involving human subjects (*in Dutch: medisch ethische toetsing commissie METC*) at the Academic Medical Centre (AMC). If you wish to find about more about the ethics committee, you can contact mecamc@amc.uva.nl. Reference W17_117.136.

[57] EASA is mandated to perform a continuous review of the effectiveness of the provisions concerning flight and duty time limitations and rest requirements contained in Annexes II and III of Commission Regulation (EU) No. 965/2012. This instruction is formalised in paragraph 9a of this Regulation.

**Purpose of the study**
The purpose of the study is to collect aircrew data on fatigue, alertness and sleep. With this data we want to detect the prevalence of high levels of fatigue in two specific envelopes of aircrew duty periods within the new FTL regulation.

The two duty envelopes that are the specific focus of this study are:

- Duties of more than 10 hours at the less favourable time of the day. This refers to operations that encroach (part of) the night (the period between 02:00h and 04:59h); and
- Disruptive schedules. This refers to repetitive early starts, late finishes, night duties, and combinations thereof. A disruptive schedule means a crew member's roster which disrupts the sleep opportunity during the optimal sleep time window by comprising a duty or a combination of duties which encroach, start or finish, during any portion of the day or of the night.

You are being invited to take part in this research study because your flight duties match one or both of these envelopes of aircrew duty periods.

**What participation involves**
This study will involve your participation in a measurement campaign of 14 consecutive days. Each day you will be asked – during your normal flight duties and during days off – to regularly fill in different rating scales, for some of you to continuously wear an actigraph (wrist-worn, watch-like device), to keep a sleep log, and to perform a reaction time test (the latter only applies for pilots). In total this will take about 15 to 20 minutes of your time per day. The assessments will be made on an application that you can download on your smartphone or tablet.

In order to carry out the study properly, it is important that you follow the prescribed study instructions. The study instructions mainly require that you to adhere to the measurement protocol as directed; meaning that you should wear the actigraph at all times and complete the assessments at the times indicated.

Before the measurements start, you will be instructed on what is expected from you throughout the 14 days. You will be trained on how to download, use and fill in the required data collection app on your smartphone or tablet.

**Possible benefits and disadvantages**
It is important that you properly weigh up the possible benefits and disadvantages before you decide to join.

You will not personally benefit from participation in this study. Your participation will contribute to answering the question whether the current fatigue management measures are consistent with the delivery of the required levels of safety for commercial aviation.

Personalised feedback based on the data gathered will not be provided by the study team.

A disadvantage in the study is the required effort that comes along with completing the measures such as rating scales and performing the 5-minute reaction time test. Per day this will take you about 15 to 20 minutes. We ask you to keep this up for a total period of 14 days.

Another disadvantage is the fact that we ask you to complete the measures during your normal flight duties, so in flight. The measurements must be carried out so that it will under no circumstances interfere with the flying task. The moments of the measurement are determined based on common practices in this type of fatigue measurement campaign. The protocol has been reviewed and approved by both the Scientific Committee and the Mirror Group in which scientific and operational aviation experts are seated.

We ask some of you to wear an actigraph (watch) for a period of 14 days, so day and night. This may result in some discomfort.

Participation in the study may lead to incidental findings about your sleeping behaviour. Based on actigraph readings, it is possible to detect sleeping behaviour outside normal values. Although the analysis of the data is not focused on such detections, and therefore changes are very low, it is still possible that we come across these deviations in the dataset. In the unlikely scenario that indications of a possible sleep disorder are found, crew will be made aware and encouraged to seek medical advice and assistance if necessary.

You will not be paid for your participation in this study. However, you have the chance of winning a prize (gadget of about 150€). A raffle will be run among the 25% of participants within your operator airline that uploaded the most valuable data. 'Valuable' will be a weighted sum of number of days covered, number of assessments and the coverage of sleep/wake logs registering actual sleep.

**If you do not want to participate or you want to stop participating**

It is up to you to decide whether or not to participate in the study. Participation is entirely voluntary.

If you do participate in the study, you can always change your mind and decide to stop, at any time during the study. The data collected until that time will still be used for the study, unless you ask us not to.

If there is any new information about the study that is important for you, the investigator will let you know. You will then be asked whether you still want to continue your participation.

To be clear: Your participation in the study stops when:

- You choose to stop; or
- The end of your data collection period has been reached after 14 days.

**Usage and storage of your data**

The gathered data will remain confidential and be processed anonymous since the identification of the aircrew and airline is irrelevant to the needs of the study. The collected data will be transferred (via encrypted technology) and stored in a password-protected central database repositories that can be accessed by study team members only; i.e., excluding EC and EASA. The collected datasets will not be disclosed to third parties by the consortium during or after the study's lifetime or beyond. Only aggregate data will be handed to EC and EASA.

The handling of personal data will comply with the Dutch personal data protection act (*in Dutch: Wet Bescherming Persoonsgegevens, WBP*). The data (without your name and airline operator) will be kept for 15 years. Data is disposed properly after this.

**Any questions?**
If you have any questions, please contact the principal investigator Dr Henk van Dijk.

Dr Henk van Dijk
NETHERLANDS AEROSPACE CENTRE (NLR)
henk.van.dijk@nlr.nl / +31885113504

You can also ask the following independent experts:

Co-chairmen of FTL Scientific Committee:

Barbara Stone
FRMSc
barbara.stone@frmsc.com

Alexandra Holmes
Clockwork Research
alex@clockworkresearch.com

**Signing the consent form**
When you have had sufficient time for reflection, you will be asked to decide on participation in this study. If you give permission, we will ask you to confirm this in writing on the appended Informed Consent Form. By your written permission you indicate that you have understood the information and consent to participation in the study. The signature sheet is kept by the investigator.

Thank you for your attention.

# Appendix 2: Informed consent

**Review of the effectiveness of the EU flight time limitation regulations for aircrew**

I, the undersigned, confirm that (*please tick box as appropriate*):

| | | |
|---|---|---|
| 1. | I have read and understood the information about the project, as provided in the Participant Information Sheet | ☐ |
| 2. | I have been given the opportunity to ask questions about the study and my participation. My questions have been answered to my satisfaction | ☐ |
| 3. | I know that participation is voluntary | ☐ |
| 4. | I understand I can withdraw at any time without giving reasons and that I will not be penalised for withdrawing nor will I be questioned on why I have withdrawn | ☐ |
| 5. | I understand that the study will not identify me by name in any reports, and that my confidentiality as a participant in this study will remain secure. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions | ☐ |
| 6. | I want to participate in this study | ☐ |

Name of study participant:

Signature: Date: __ / __ / __

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I hereby declare that I have fully informed this study participant about this study.

If information comes to light during the course of the study that could affect the study participant's consent, I will inform him/her of this in a timely fashion.

Name of investigator (or his/her representative):

Signature: Date: __ / __ / __

# Appendix 3: Study parameters

| Name | Type | Label | Values | Missing | Measure | Remarks | Type of study parameters |
|---|---|---|---|---|---|---|---|
| PN | String | Participant number | - | - | Nominal | - | Other |
| Crew | String | Type of aircrew | 1. Captain<br>2. First officer<br>3. Cabin | 9999 | Nominal | - | Other |
| Acti | String | Wearing actigraph | 1. Yes<br>2. No | 9999 | Nominal | Not all aircrew are wearing actigraphs | Other |
| PVT | String | Performing PVT | 1. Yes<br>2. No | 9999 | | Not all aircrew is performing PVT | Other |
| Home | String | Home base | 0 - 32 | 9999 | Nominal | EASA Member States | Other |
| Day | Number | Day number | 1 - 14 | 9999 | Nominal | - | Other |
| Gender | String | Gender | 1. Male<br>2. Female | 9999 | Nominal | - | Other |
| Age | Number | Age | - | 9999 | Ratio | Age in years | Other |
| Hght | Number | Height | - | 9999 | Ratio | Height in centimetres | Other |
| Wht | Number | Weight | - | 9999 | Ratio | Weight in kilograms | Other |
| HabSlp | Number | Habitual sleep length | - | 9999 | Ratio | Time in minutes | Other |
| ComTime | Number | Typical commute time at home base | - | 9999 | Ratio | Time in minutes | Other |
| Diurn | String | Diurnal type | 1. Extreme eveningness<br>2. Eveningness<br>3. Intermediate<br>4. Morningness<br>5. Extreme morningness | 9999 | Nominal | - | Other |
| FDPtype | String | FDP type | 1. FDP1<br>2. FDP2 | 9999 | Nominal | FDPref refers to the duties 'outside' FDP1 and FDP2 that can be used as reference or control duties | Other |
| FDPstart | Number | Start of FDP | 0 - 1439 | 9999 | Ratio | Time in min from 00:00h in the time zone the participant is/was last acclimatized to | Other |
| FDPend | Number | End of FDP | 0 - 1439 | 9999 | Ratio | Time in min from 00:00h in the time zone the participant is/was last acclimatized to | Other |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| FDPdur | Number | Duration of FDP | - | 9999 | Ratio | FDPend - FDPstart | Other |
| TimeZoneD | Number | Change of time zone | -12 - +12 | 9999 | Ratio | E.g. -3 means 3 hours earlier than time zone to which the crew member is/was last acclimatized to | Other |
| Sect | Number | Number of sectors | - | 9999 | Ratio | Number of sectors flown per duty | Other |
| ME | Number | Mental effort | 0 - 150 | 9999 | Ratio | Rating scale mental effort | Other |
| Hssl | String | Hassle factors | 0 - 21 | 9999 | Nominal | Listed hassle factors | Other |
| KSSstart | Number | KSS start of duty | 1 - 9 | - | Ordinal | KSS 1 - 9 | Primary |
| KSSTOD* | Number | KSS final leg Top of Descent | See KSSstart | - | Ordinal | - | Primary |
| KSScrs | Number | KSS cruise long night flight | See KSSstart | 9999 | Ordinal | - | Primary |
| SPstart | Number | SP start of duty | 1 - 7 | - | Ordinal | SP 1 - 7 | Primary |
| SPTOD* | Number | SP final leg Top of Descent | See SPstart | - | Ordinal | - | Primary |
| SPcrs | Number | SP cruise long night flight | See SPstart | 9999 | Ordinal | - | Primary |
| PVTstartRT | Number | PVT response time at start of duty | - | 9999 | Ratio | Mean response time | Secondary |
| PVTTODRT | Number | PVT response time at final leg Top of Descent | - | 9999 | Ratio | Mean response time | Secondary |
| PVTstartLap | Number | PVT number of lapses at start of duty | - | 9999 | Ratio | Number of lapses | Secondary |
| PVTTODLap | Number | PVT number of lapses at final leg Top of Descent | - | 9999 | Ratio | Number of lapses | Secondary |
| SlpWk | Number | Sleep-wake ratio | - | 9999 | Ratio | LogTST divided by amount of wakefulness Calculated for duty days covering the period from beginning of the main sleep that preceded | Primary |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | an FDP until the end of the FDP | |
| LogTST | Number | Total sleep based on sleep log | - | 9999 | Ratio | Time in minutes; based on difference between LogBed and LogWake | Primary |
| LogBed | Number | Time of falling asleep based on sleep log | - | 9999 | Ratio | Time in minutes; used to determine LogSlp | Other |
| LogWake | Number | Time of falling asleep based on sleep log | - | 9999 | Ratio | Time in minutes; used to determine LogSlp | Other |
| ExtAwa | String | External awakening after sleep based on sleep log | 1. Yes<br>2. No | 9999 | Nominal | - | Other |
| ActTST | Number | Total sleep based on actigraph | - | 9999 | Ratio | Time in minutes | Primary |
| ActSlp | Number | Sleep based on time in bed (actigraph) | - | 9999 | Ratio | Time in minutes | Other |
| ActBed | Number | Time of falling asleep based on actigraph | 0 - 3599 | 9999 | Ratio | Time in minutes | Other |
| ActWake | Number | Time of waking up based on actigraph | 0 - 3599 | 9999 | Ratio | Time in minutes | Other |

*The KSS TOD and SP TOD parameters are measured in-flight not only in the final leg, but also in all other legs. These are not included in the table but are similar to KSS TOD and SP TOD.

European Commission