

**Department of Transportation
Federal Aviation Administration Office of Environment and Energy**

**SUPPORTING STATEMENT
Supporting Statement for a New Collection:
National Sleep Study
OMB Control Number 2120-XXXX**

INTRODUCTION

This information collection is submitted to the Office of Management and Budget (OMB) to request a three-year approval clearance for the information collection entitled National Sleep Study (OMB Control No. 2120-XXXX).

Part A. Justification

1. Circumstances that make collection of information necessary.

Currently, the Department of Transportation Federal Aviation Administration (FAA) defines a significant noise threshold as a Day-Night Average Sound Level (DNL) of 65 decibels (dB) or more. In 1979, through the *Aviation Safety and Noise Abatement Act (ASNA) of 1979*, FAA implemented the ASNA's provisions in Part 150. This regulation adopted the DNL metric and the 65 dB land use compatibility guideline. DNL 65 dB was chosen because it balanced environmental goals with technical and economic feasibility. In 1992, the Federal Interagency Committee On Noise (FICON) reevaluated DNL and 65 dB and confirmed their continued use for stated purpose (Federal Interagency Committee On Noise (FICON), 1992). This was the last in-depth government agency review on the metric and measure. In addition, even though DNL 65 dB contours around airports have decreased over the last 30 years, community opposition and challenges regarding aircraft noise have increased. The FAA believes this is due in part to changes in the nature of aircraft operations. Although most of the commercial airline fleet is newer and quieter, the sheer *number* of flight operations (particularly at the largest and busiest airports) has increased over the last 30 years.

Undisturbed sleep of sufficient length is of paramount importance for the maintenance of health and well-being (Watson et al., 2015). The auditory system has a watchman function and is constantly monitoring our environment for threats, including while we sleep. Noise has been shown to be a potent disruptor of sleep (M. Basner et al., 2014), and is considered one of the most important environmental effects of air traffic (M. Basner, Griefahn, & van den Berg, 2010).

With the most recent United States (U.S.) sleep study dating back to 1996 (Fidell, Pearsons, Tabachnick, & Howe, 2000), U.S. research on the effects of

aircraft noise on sleep, particularly compared to the efforts of some European countries, has lagged over the past 20 years. Also, past U.S. studies on the effects of aircraft noise on sleep predominantly used the so-called “push button” methodology, where study participants were required to push a button whenever they woke up during the night. This method has been shown to have low sensitivity, as most awakenings are too short for subjects to regain waking consciousness and initiate a response (M. Basner, Brink, & Elmenhorst, 2012). Therefore, most awakenings relevant for sleep recuperation are missed by this methodology.

Due to inter-cultural differences and different operational procedures, results from studies performed outside the U.S. may not translate directly to U.S. domestic airports. Therefore, it is important that field studies be conducted in the U.S. to acquire current data on sleep disturbance relative to varying degrees of noise exposure. For this purpose, a new study methodology was developed and validated to unobtrusively measure noise-induced awakenings with a small device attached to the chest with only two electrodes (M. Basner, Griefahn, Muller, Plath, & Samel, 2007; M. Basner, Müller, Elmenhorst, Kluge, & Griefahn, 2008; McGuire, Müller, Plath, & Basner, 2014). The device measures body movements and heart rate, two variables strongly associated with awakenings (M. Basner et al., 2007). This methodology has been piloted at two U.S. airports (Philadelphia and Atlanta) and was found to be feasible for a larger-scale national study, which is a purpose of this collection. The main purpose of the National Sleep Study is to collect nationally representative information on the effects of aircraft noise on sleep in order to derive exposure-response relationships between the A-weighted maximum sound pressure level $L_{AS,max}$ of single aircraft noise events, expressed in dB, and the likelihood of waking up, expressed as a percent chance (0-100%).

The study population of the National Sleep Study is residents living close to airports, who are exposed to nighttime noise from air traffic. Since airports differ in nocturnal flight operations and pattern, it will be necessary to investigate several airports across the U.S. that are representative for all U.S. airports with relevant nocturnal air traffic to achieve this goal. Night time aircraft noise exposure for the sampling population will be assessed using the A-weighted average maximum sound pressure level with a slow (1 s) time weighting ($L_{AS,max}$) and the long-term energy-averaged sound pressure level during the nighttime (22:00-07:00) period (L_{night}), both expressed in dB. According to FICON, the maximum level of a single flyover ($L_{AS,max}$) is useful for analyzing short-term responses (Federal Interagency Committee On Noise (FICON), 1992). L_{night} , when weighted to account for the additional possibility of activity disturbance by noise at night, forms the basis of the night component of DNL, which is an industry standard.

2. How, by whom, and for what purpose is the information used.

The FAA will use the information from this collection to support potential updates to or validation of the national aviation noise policy, to determine community noise impacts, land-use guidelines around airports according to 14 CFR Part 150, and abatement and mitigation action. In-home measurements of noise, heart rate and body movements will be performed to investigate the degree of aircraft noise-induced sleep disturbance depending on the noise level of individual aircraft as experienced in the bedroom. A postal survey will be sent to addresses in the vicinity of airports with relevant nocturnal air traffic. The survey collects information about general health and sleep health, demographics, non-health exclusion criteria, and supplementary outcomes for non-response and non-participation analyses. The mailing includes a \$2 incentive for filling out and returning the survey. Each address will only be contacted once. However, in case of no response, individual households will receive up to 3 follow-up mailings. Eligibility to participate in the in-home sleep study will be determined based on answers provided in the recruitment survey. Respondents must be eligible and indicate that they are interested in participating in the in-home sleep study to be contacted by the research team for the purpose of enrolling them into the in-home study. Respondents will provide written informed consent prior to participating in the in-home sleep study, which is performed under the oversight of the Institutional Review Boards (IRB) of the University of Pennsylvania and Westat. Participants will be reimbursed for their time participating in the in-home sleep study with up to \$170. Response to the recruitment survey and participation in the in-home sleep study are voluntary. The University of Pennsylvania and Westat (recruitment survey data only) will receive the information. Data will not be shared with DOT, FAA, other entities or the public. Data analysis results will be published in reports to FAA and in the peer-reviewed scientific literature making sure that individual respondents cannot be identified. Data will be collected in a coded fashion. Personally Identifiable Information (PII) will be stored at the University of Pennsylvania and Westat on secure computers until data analyses are finalized and reports have been published. At that time, the IRB protocols will be closed and PII will be destroyed.

3. Extent of automated information collection.

In the postal survey, which has the primary purpose of recruiting participants for a subsequent field study, data collection will be conducted using a paper questionnaire. In the field study, data will be collected using paper questionnaires, a sound recorder in the bedroom, and a heartrate and body movement monitor on the torso of participants. The sound recorder and the heartrate and body movement monitor will provide the primary measure of estimating the dose-response relationship between aircraft noise and awakenings.

For the postal survey, an information technology system will be used to track respondents and to record, store and maintain the data. Conducting a web survey, rather than a postal survey, would not permit adequate coverage of those that do not have access to the Internet (Dillman, Smyth, & Christian, 2014; Messer & Dillman, 2011). In addition, contacting individuals by mail allows us to include a \$2 cash incentive, which can significantly increase response rates (Church, 1993; Dillman et al., 2014; Edwards et al., 2009). Finally, postal surveys yield significantly higher response rates than web surveys (Dillman et al., 2014; Manfreda, Bosnjak, Berzelak, Haas, & Vehovar, 2008). Some consideration was given to providing the respondents a choice between a paper mail and a web survey. This was rejected because a number of studies have found that giving respondents a choice depresses response rates (Dillman et al., 2014). We will instead follow standard procedures given by (Dillman et al., 2014) and initially offer the option to respond by mail only, and provide the possibility of replying online in follow-up survey mailings only.

4. Efforts to identify duplication.

Most previous U.S. investigations into the effects of aircraft noise have relied on self-reported annoyance data obtained via surveys. Self-reported annoyance by aircraft noise is at best a proxy for objective sleep disturbance, since annoyance is not exclusive to effects on sleep and is influenced by individual characteristics such as noise sensitivity and attitude to the noise source. Furthermore, sleep is by definition spent in an unconscious state, which makes it difficult to self-assess since the individual is unaware of how they are reacting to the noise unless they are fully awoken by the noise and recall this awakening the following morning. Since self-assessment leads to possible errors, more objective measures are needed. Past U.S. studies on the effects of aircraft noise on sleep predominantly used the so-called “push button” methodology, where study participants were required to push a button whenever they woke up during the night. This method has been shown to have low sensitivity, as most awakenings are too short for subjects to regain waking consciousness and initiate a response (M. Basner et al., 2012). Therefore, most awakenings relevant for sleep recuperation are missed by this methodology, and physiologic measurements of sleep are needed.

There have not been any previous studies in the U.S. where physiologic data, either body movements or heart rate, were collected from residents living in the proximity of airports, apart from two pilot studies where we validated that collecting these data was feasible. As such, the current study is a unique and comprehensive study that would be the first on a scale larger than a single airport. Furthermore, the current study will collect information about measured, rather than estimated, levels of aircraft noise inside of residents' bedrooms. A further aspect differentiating the current investigation from

earlier work is the scale of the effort. Typically, the earlier studies were conducted around one or a small number of selected airports. The current study is addressing all U.S. airports that have a sufficient number of nighttime operations.

5. Efforts to minimize the burden on small businesses.

This effort will not impact small businesses or other small entities.

6. Impact of less frequent collection of information.

This is a single measurement campaign that spans over 2 years. The required sample size has been determined by power calculations provided in Part B. Information on measured indoor aircraft noise levels and physiologic response has never previously been collected on a national level in the U.S., and was only previously collected in two pilot studies where we validated that collecting these data was feasible. This current and high-fidelity information is required to assess immediate and objective community impact of aviation, as it is critical to collect updated data on potential effects on sleep. The existing scientific data are outdated and lack fidelity of new modern techniques of data collection. Failure to update data and relationships will cause the FAA to continue to rely on data that are at least 20 years old, and continue to have the public and members of Congress question the validity of the current level of significance.

7. Special circumstances.

EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE THIS INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:

▪ **REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY;**

No participant will be asked to provide information more often than quarterly. Responding to the postal survey and, if appropriate and desired by the respondent, participation in the five-night field study will be a one-time event.

▪ **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT;**

The postal survey is not a mandatory data collection. We are however requesting that surveys are completed within fourteen days of receipt, which is intended to convey the time frame under which the study is operating. This follows standard procedures as followed in (Dillman et

al., 2014).

- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**

No respondent will be asked to submit more than the original copy of a data collection instrument.

- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN THREE YEARS;**

No participant will be asked to retain records for more than three years. Respondents to the postal survey are not required to retain any records at all. Participants in the field study will retain the study equipment and documents for the duration of the five-night study and will be returning everything upon completion of their participation, at which point they are not required to retain any records. The only document that participants in the field study can, but do not have to, retain is a copy of the signed informed consent form.

- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**

No invalid statistical survey is anticipated.

- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**

No unapproved data classification activities are anticipated.

- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUTE OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR**

All pledges are supported by the authority established in statute or regulation.

- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED PROCEDURES TO PROTECT THE INFORMATION'S CONFIDENTIALITY TO THE EXTENT PERMITTED BY LAW.**

No trade secrets or items of similar confidential information will be requested.

8. Compliance with 5 CFR 1320.8.

A notice was published in the Federal Registry on November 27, 2019 (vol. 84, no. 229, pgs. 65453-65454).

There were seven responses to this notice. The notice received comments from members of the public and Airlines for America, the principal trade and service organization of the U.S. airline industry.

Five comments demonstrated disturbance of sleep by aircraft noise by residents living near an airport. These comments show that further research into the effects of nocturnal aircraft noise is required, justifying the need for the National Sleep Study. In two comments (4.1-4.10 and 7.1-7.3) there were clarifying questions on the postal survey questions and sampling procedure, the field study methodology and sample sizes. We have responded to each question in point below.

Comment 4.1. The test sample must be representative of the population, which means you must include people of all different age groups, including babies through retirees who may have different sensitivities to a noise event. How are you going to calculate in this instance if a baby woke up, that it then work up its parents? So one noise event impacted 3 residents in one home; not 1 resident in one home. Is the study per household?

Response to comment: For ethical reasons, this study will include consenting adults who are at least 21 years of age only. There is no upper age limit, and a representative spread of age ranges is expected.

Secondary effects of noise-induced awakenings, for instance an infant awoken by aircraft noise subsequently waking the parents, are outside the scope of this study. That said, sleep architecture changes with age, with the relative amounts of deep sleep decreasing as one ages. Arousal thresholds are higher during these deeper sleep stages; thus, we anticipate that infants and children are less likely to wake up to a given noise event than adults.

We are seeking a single respondent per household mailed. To ensure a representative sample, we are adopting a pseudo-randomized sampling procedure by specifying that the survey respondent should be the person in the household who will next celebrate a birthday.

Comment 4.2. Your sample size appears too small. It does not appear sufficiently correlated to the number of US airports; complaints against airports; number of people complaining (i.e., you do not have enough coverage relative to the population of potentially impacted individuals). Have you included people you know have made noise complaints to airports or

avoided reaching out to people who have made noise complaints? If you do not include people who have knowingly made noise complaints, particularly those who are awoken at night, why would you not include some of those people in your sample? There are over 1.5 million complaints against Burbank Airport since Nextgen implementation. Are you including residents in any of those areas of complaints (Studio City, Sherman Oaks, Beverly Glen, Encino)? Are you including residents impacted by the 24-hr flight operations from Van Nuys Airport?

Response to comment: The sample size of 400 participants in the field study was based on effect sizes of aircraft noise induced awakenings from four previous studies, including two pilot studies in the U.S. (Philadelphia and Atlanta). As described in Part B.1.3., this sample size of 400 was determined by the number needed to estimate the probability of awakening to an event with a maximum sound pressure level with an A-weighted response and slow (1 s) time constant of 50 dB when the background equivalent sound pressure level with an A-weighted response in the bedroom is 30 dB, with a 95% confidence interval half-width no larger than 0.015.

As described in B.1.1, all airports in the U.S. with a runway that have, on average, a minimum of one aircraft operation (departure or arrival) per hour during the nighttime (22:00-07:00) are included in the sampling frame. Among these airports, we required that airports maintain medium-high traffic during a typical sleep period, as determined by our pilot data. The addresses to which we will mail a total of 24,500 postal surveys will be selected by stratified random sampling. In this way, every resident exposed to a relevant amount of nighttime aircraft noise has an equal probability of being contacted to take part in the study. The complaints were not considered during airport selection.

Comment 4.3. You cannot assume an airport applies any curfew, since many don't. So are you including the possibility of noise events that impact sleep from these airports also, or only ones that don't have a curfew? Actual flight traffic volume and patterns should be analyzed vs. Airport hours only to ensure comprehensive coverage.

Response to comment: The determination whether an airport had enough nighttime air traffic to be part of the sampling frame was based on actual traffic data at all US airports for the year 2018. Airports that apply curfews but do not adhere to them are still part of the sampling frame if they met minimum criteria for nocturnal air traffic (i.e., at least 1 aircraft noise event per hour for a given runway end). Our physiologic analysis involves acoustic measurement in the bedroom over five consecutive nights, rather than relying on noise prediction models. In this way, all aircraft noise events during sleep will

be captured.

Comment 4.4. An "event" must be clearly defined and an additional penalty/adverse impact be applied for repeat "events" during the sleep cycle period that result in multiple interruptions (or have the propensity to do so), such that the cumulative impact on an individual's quality of sleep in 1 day, and over a period of time is correctly measured. There needs to be an adverse penalty calculation factor for multiple interruptions.

Response to comment: Aircraft noise events in our analysis are defined as the maximum sound pressure level of the aircraft noise emerging from the background level in the bedroom, and with no concurrent noise from e.g. road or rail traffic. Statistical analysis of aircraft noise induced awakenings will include the number of aircraft noise events during the night as a covariate in the regression models.

Comment 4.5. Will you be calculating how long it takes someone to get back to sleep? if so how? The mere interruption of sleep is not a sufficient factor to determine the true impact on an individual if it takes that individual 2 hours to get back to sleep. It is the "quantity" of minutes/hours of lost sleep per event + frequency of events in a given period of time (with cumulative adverse factor) that must be measured.

Response to comment: In addition to recording ECG, with which we will determine physiologic awakenings, we are also recording body movements with actigraphy. We will use actigraphy to determine sleep onset latency and total sleep time. This will include wakefulness after sleep onset, including long-duration awakenings due to aircraft noise.

Comment 4.6. All air traffic must be considered to create an "event" - helicopters; general aviation; charter/transportation carriers (e.g., Fedex); commercial jets; military aircraft.

Response to comment: Trained personnel identify and mark the different types of air traffic by listening to audio files. The focus of this study is on aircraft with jet engines. However, trained personnel will identify and mark the different types of air traffic by listening to the audio files. However, helicopters are not included.

Comment 4.7. You cannot limit this Study to areas in the immediate vicinity of the airport where you already know there is a 65DNL environment. Since NEXTGEN has created so much concentration of frequent, low altitude helicopters, general aviation and jets miles away from airports (i.e., 3-12 miles away from Burbank Airport, SoCal) the residents now impacted by noise and woken up by noise has shifted. Many of these areas are still not considered to be within a "flight path" based on historical designations. NEXTGEN has destroyed the quality of life and significant noise impact for

many of us in these new flight paths who are routinely woken up at night. Since most of the Airports have no noise monitors in these areas; how are you going to ensure this most significantly impacted population of residents is included in your sample? It needs to be.

Response to comment: We are using night- time level L_{night} , not DNL, to choose study areas. All residents residing in areas with at least 40 dB nighttime exposure around eligible airports will be eligible to receive a recruitment survey for the field study. These areas extend substantially beyond DNL 65 dB. Furthermore, we will perform actual acoustic measurements in the bedrooms, and will not rely on modelled, averaged noise metrics to determine the noise exposure of all participants in the field study.

Comment 4.8. If the FAA applies its existing noise model using its current 65DNL, etc. as the metric to determine a noise event actually occurred or could have had any "significant impact or no impact", this study will be fundamentally flawed. You cannot use your existing measurement system to determine what has a significant impact or not. The relevant factors for this study are an aircraft event and sleep disturbance; not whether the FAA thinks the decibels and any changes in these per your existing noise metrics, are insignificant or significant. This noise model is outdated and completely understates the impact in noise sensitive areas where decibels increase from 40 to 80 in one single event. What matters is that any aircraft flew within some vicinity of the home that caused a sleep disturbance. You also cannot limit the distance or altitude you deem an event to have a causal impact on sleep, as varying terrain resonance, different types of aircraft noise can travel significant distances.

Response to comment: During this study, sound pressure levels in the bedroom will be obtained through measurement, not by modeling. These measurements will be used to identify the exact times and sound pressure levels of all aircraft events during the night. All noise events identified in these acoustical measurements will be included in analysis, regardless of how near or far the aircraft is from the residence, or the altitude at which the aircraft is flying. Modeling will be used only to ensure a wide range of aircraft noise levels in the bedrooms.

Comment 4.9. How is the FAA going to determine an aircraft event caused a sleep disturbance? Are you planning on using current fitbit, iphone, other applications that indicate disturbance in conjunction with other more expensive measurement equipment? This could increase the sample size at lower cost.

Response to comment: We will determine awakenings via analysis of the electrocardiogram and body movements using a validated

algorithm (M. Basner et al., 2007). The electrocardiogram and body movements will be measured with a single device attached with an electrode to the chest. Aircraft noise will be measured continuously in the bedroom. Equipment will be mailed to participants, who then set it up on their own and mail it back after the study is complete. This approach has been shown to be feasible in a pilot study around Atlanta airport (Mathias Basner, Witte, & McGuire, 2019). This allows us to investigate a large sample size around multiple airports.

We will not use commercial sleep devices such as FitBit or commercial smart phone applications since these are insensitive to detecting awakenings. Furthermore, devices such as these use proprietary algorithms to score sleep that have been shown to only partially concur with more accurate measures of sleep architecture such as polysomnography (Haghighyegh, Khoshnevis, Smolensky, Diller, & Castriotta, 2019).

Comment 4.10. Your sample must accommodate sleep cycle for people who work night shift and must obtain daytime sleep.

Response to comment: Background noise levels are higher during the daytime than at night, thus any given discrete aircraft noise event needs to be higher level to emerge from the background and potentially induce an awakening. Because there would likely be increased noise levels from road, rail, neighbors, industrial/commercial activity and/or construction, it would be increasingly unlikely to identify aircraft noise as the primary cause of a given awakening, as responses could be due to any or all of these other anthropogenic noise sources. Furthermore, sleep pressure of shift workers may be increased or decreased depending on how well they are adapted to their shift schedule. For these reasons, this study thus focuses on subjects who are not working more than 6 hours during the period 10 pm until 7 am, which is the vast majority of the population, e.g. a 4.4% prevalence of night-shift work in the U.S. adult population was reported recently (Yong, Li, & Calvert, 2017).

Comment 7.1. First, while the ICR states FAA will conduct a postal survey and field study to gather empirical data to derive an exposure-response relationship between aircraft noise and sleep disturbance, it is completely devoid of the content of either methodology. This omission prevents A4A from being able to assess whether FAA's proposal will ensure data quality in the survey and field study responses. For example, FAA provides no detail on the questions the postal survey will include to assess whether they contain any bias or if the survey will include questions allowing the agency to perform logic tests for quality assurance. Similarly, no details are provided on how the field study will be conducted to assess whether FAA will be able

to ensure data quality across participants. For example, FAA provides no indication of how it will record aircraft noise events or residents' waking up to assess whether the field studies will be able to ensure sleep disturbance occurrences are due to aircraft noise rather than other environmental exposures or participant attributes that could cause sleep disturbances aside from aircraft noise exposure. Without additional details, A4A is unable to provide the type of comments FAA is explicitly seeking in this *Federal Register* notice.

Response to comment: The rationale for each survey question is described in detail in Appendix L.

To obtain quality data in the field study, two pilot studies were performed, one around Philadelphia (PHL) airport and another around Atlanta (ATL) airport, and suitability of measurement by unattended equipment was confirmed (see, for example Basner et al. 2019 Int J Env Res Pub Health 16(17) and Smith et al. 2020 Sci Tot Env 718).

Aircraft noise events will be obtained from acoustic readings in the bedroom, this method was validated in a pilot study around Atlanta International Airport, and described in section B.2.2. Individuals with sleep disorders will be excluded from study based on their responses in the recruitment survey.

Comment 7.2. The ICR states that the "main purpose of the National Sleep Study is to collect nationally representative information" about single aircraft noise events and resident's waking up, yet it does not explain in any detail how FAA plans to ensure the information it collects will in fact be "nationally representative." Rather, the ICR states the information will simply be collected through postal surveys and follow-up field studies without any detail explaining how the postal survey will be distributed or how follow-up field studies will be conducted to be effective in obtaining high-quality, nationally representative data. Furthermore, the ICR is silent as to how a postal survey will be an effective survey methodology to ensure objective information is collected. The National Sleep Study will be used to "derive exposure-response relationships between aircraft noise and its effect on communities around United States civilian airports," so FAA will likely send its postal survey to communities around U.S. civilian airports. These communities contain both residents who are and who are *not* concerned about aircraft noise, yet the ICR does not explain how FAA will ensure both types of residents will be represented in the survey and follow-up field studies. Arguably, those residents who are concerned about aircraft noise likely are more willing to take the time and effort to fill out a postal survey than those residents who do not see aircraft noise as an issue. It follows, then, that postal survey responses could very well be distorted by a disproportionate number of "concerned" responses finding a larger purported impact on sleep from aircraft noise exposure than is actually the

case with the population at large.

Response to comment: As described in B.1.1, all airports in the U.S. with a runway that have, on average, a minimum of one aircraft operation (departure or arrival) per hour during the nighttime (22:00-07:00) and have medium-high traffic during a typical sleep period are included in the sampling frame.

The primary purpose of the postal survey is to recruit study participants for a field study with a physiologic and objective measurement of sleep. It is these physiologic data that will be used to derive the exposure-response relationships. The mailing addresses will be selected in a random fashion, in such a way that every resident exposed to a relevant amount of nighttime aircraft noise has an equal probability of being contacted to take part in the study. This will likely include residents who both are and are not concerned about airport noise. The mailing strategy that would maximize the response rate, and thus reduce the risk for response bias, was used in a pilot study around Atlanta airport and is as described in Smith et al. 2019 (BMC Med Res Meth 19: 230).

In the postal survey we are collecting information on annoyance and sleep disturbance by aircraft noise using standard phraseology in order to compare annoyance and sleep disturbance, among respondents, of those who participate and do not participate in the field study. An analysis of differences between participants and non-participants based on demographic questions will be performed.

Comment 7.3. Finally, the ICR states that this information will be used “to inform any potential updates to or validation of the national aviation noise policy.” The national aviation noise policy substantially impacts, for example, land uses around airports, the disbursement of tens of millions of dollars in federal grants to mitigate aircraft noise in communities near airports, and the investment in research and development programs like ASCENT and CLEEN noted above. Consequently, the National Sleep Study could be quite influential to the trajectory of U.S. aviation, making the robustness of this ICR, the first step in the process, critical. The lack of detail in this ICR is therefore troubling. As the ICR currently does not provide information on how FAA will obtain high-quality, objective and nationally representative data through a scientifically robust process, we request FAA provide additional detail in its ICR to OMB to show how it will ensure data objectivity, integrity and quality through its collection of information for the National Sleep Study. Thank you for your consideration. Please let us know if you have any questions regarding our comments or would like to discuss them in greater detail.

Response to comment: The OMB submission will include detailed

information on data objectivity, integrity and quality. For complete transparency, the pilot study findings are also published in peer-reviewed scientific journals, including for example:

Smith MG, Rocha S, Witte M, Basner M. On the feasibility of measuring physiologic and self-reported sleep disturbance by aircraft noise on a national scale: A pilot study around Atlanta airport. *Sci Tot Env*. 2020;718:137368. Published 2020 May 20. doi:10.1016/j.scitotenv.2020.137368

Smith MG, Witte M, Rocha S, Basner M. Effectiveness of incentives and follow-up on increasing survey response rates and participation in field studies. *BMC Med Res Methodol*. 2019;19(1):230. Published 2019 Dec 5. doi:10.1186/s12874-019-0868-8

Rocha S, Smith MG, Witte M, Basner M. Survey Results of a Pilot Sleep Study Near Atlanta International Airport. *Int J Environ Res Public Health*. 2019;16(22):4321. Published 2019 Nov 6. doi:10.3390/ijerph16224321

Basner M, Witte M, McGuire S. Aircraft Noise Effects on Sleep-Results of a Pilot Study Near Philadelphia International Airport. *Int J Environ Res Public Health*. 2019;16(17):3178. Published 2019 Aug 31. doi:10.3390/ijerph16173178

9. Payments or gifts to respondents.

There will be three types of incentives for participants in the study: an incentive for completing the postal survey, an incentive to take part in the field study, and incentives for providing additional demographic and sleep data during participation in the field study.

A \$2 cash incentive will be included in the first mailing of the postal survey questionnaire package. Pre-paid incentives of this size have been shown to significantly increase response to postal surveys (Church, 1993; Dillman et al., 2014; Edwards et al., 2009). Furthermore, in a pilot study a \$2 cash incentive almost tripled the response rate compared to promised gift cards of \$2, \$5 or \$10 value (Smith, Witte, Rocha, & Basner, 2019).

For respondents recruited into the field study, we will offer an incentive of \$30 per night, for a total of \$150, paid by sending a pre-paid debit card (ClinCard) after the study is completed. An incentive is necessary because we are requesting additional participation from the postal survey respondent.

Field study participants will be offered an incentive of \$2 for completing a questionnaire on each of the five study mornings (for a total of \$10 if the questionnaire is completed each morning), and \$10 for completing a one-time questionnaire on habitual sleep quality; morningness and eveningness (chronotype); and sensitivity to noise. These incentives will be paid after the questionnaires are completed, with the funds added to the pre-paid debit card as done for the incentive for participation in the field study noted above.

10. Assurance of confidentiality.

The study has been approved by the University of Pennsylvania's Institutional Review Board (IRB). Accordingly, respondents to the postal survey will be told "This survey was approved by the Institutional Review Board of the University of Pennsylvania (Protocol number 833863). Your participation is voluntary. All responses you provide will be kept confidential. Your contact information will not be shared."

The University of Pennsylvania has granted a waiver specifically for this study of the usual requirement that participants in the field study would be required to provide their social security number (SSN) in order to process their payment. As such, we will not be collecting or storing any SSNs.

The postal survey data will be collected by Westat, a statistical research organization, which has significant experience with conducting surveys. Westat has its own internal IRB under provisions specified by its multiple project assurance plan, and its own policy and procedures regarding assurance of confidentiality and a pledge that all employees must sign. All Westat employees have taken human subjects protection training. Westat provides all safeguards mandated by Privacy and Confidentiality Acts to protect the confidentiality of data gathered for this study. Westat data security procedures comply fully with procedural safeguards for computerized records as outlined in the U.S. Department of Health and Human Service's *General Administrative Manual* under "Safeguarding Records Contained in Systems of Record" and specified by the National Institute of Standards and Technology Federal Information Processing Standards (FIPS).

All study participants will be assigned an anonymized case ID. Westat will obtain personal contact information (name, address, telephone number) as necessary for data collection purposes. These data will be maintained in confidentiality; survey data files will use the case ID and contain identifiable data only if essential to their purpose. All materials used for mailing purposes that include personal contact information will be kept in a field room that is passcode accessible only to the field staff workers. All electronic records will be stored in secured directories accessible only by project staff with a need

to access. Westat will be required to deliver to the University of Pennsylvania the postal survey data collected to identify and recruit eligible participants into their field study. Westat will deliver these files via Westat's secure file transfer protocol (SFTP) site. Only limited Westat and University of Pennsylvania staff with need to access will be given accounts for this folder.

Data analysis will be performed by the University of Pennsylvania. All University of Pennsylvania researchers involved in the project have undertaken CITI training in Protection of Human Subjects Research. The University of Pennsylvania will store postal survey data collected by Westat on a secure server with limited access privileges and passwords. All postal survey respondents will be assigned an ID number. Code number identifiers will be kept separate from the research data.

After completion of the 5-night in-home field study, research participants will mail all study equipment and surveys back to the University of Pennsylvania. Computer-based data collected for the field study, including physiologic and acoustic data, will be downloaded from the data collection devices and stored on a secure server with limited access privileges and passwords. Consent forms and any other document with identifiable information will be kept in a locked cabinet. Data will be de-identified. Data will be kept confidential throughout the course of the research by using subject ID numbers and restricting access to data. Code number identifiers will be kept separate from the research data. The consent form reviewed and signed by all participants in the field study includes the following assurances of confidentiality:

“How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. Your name and private identifiable information will be entered into Redcap. Redcap is a secure web application designed to support data capture for research studies. All web-based surveys will also be implemented using Redcap. All consent forms and any other documents that contain your name or other identifiable information will be stored in a locked cabinet in a research office located in Blockley Hall at the University of Pennsylvania. Confidentiality will be maintained by giving you a study code and all your study information will relate to this code number. All computer based files will be kept on a secure server with limited access privileges and passwords.

What may happen to my information collected on this study?

Your information will be de-identified. De-identified means that all identifiers

have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

As part of the study, the Principal Investigator and study team may disclose your information to those listed below:

*Individuals or organizations responsible for administering the study:
Federal Aviation Administration (the funding organization)*

*Regulatory and safety oversight organizations
The Office of Human Research Protections*

Prior to the conclusion of this project, you can cancel your permission to use and disclose your information by contacting the Principal Investigator of this study. The Principal Investigator can be reached by phone or mail at the number and address listed above.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

If you join this study:

You will not own the data given by you to the investigators for this research. Any funder of this research may study the data collected from you.

You will not own any product or idea created by the researchers working on this study.

You will not receive any financial benefit from the creation, use or sale of such a product or idea.”

At the conclusion of this study, the University of Pennsylvania will deliver a final report outlining the results of the analyses outlined above to FAA. Results will be reported in aggregate form without identifying individual study participants. The University of Pennsylvania shall maintain all study information retained in accordance with National Archives and Records Administration (NARA) records retention policies and schedules and FAA policies.

11. Justification for collection of sensitive information.

None of the questions that will be included in the postal or field study questionnaires will be of a sensitive nature. Respondents to the postal survey will be asked to provide race, ethnicity, age, and annual household income bracket. These data are needed for non-response analysis, by comparing respondent demographics against census tract level demographics from the American Community Survey (ACS) and decennial U.S. census (United States Census Bureau, 2010, 2019). Questions on race and ethnicity are written according to OMB standards (Office of Management and Budget (OMB), 1997). Respondents have the option of indicating “Prefer not to answer” for the questions on race and household income.

12. Estimate of burden hours for information requested.

The hour burden for the National Sleep Study is shown in Tables A-1 and A-2 below. The postal questionnaire will take approximately 8.25 minutes (0.138 hours) to complete. The field study will involve only consenting volunteers and will take approximately 154 minutes (2.57 hours) of active participation to complete, spread across five study days and not including the time when subjects are sleeping wearing the equipment. These estimates are based on experience using these instruments in a pilot study (see Section B.4). It is anticipated the National Sleep Study instruments and procedures take a similar time to complete as those in the pilot. A burden statement will be included in the final materials issued to study participants on the Postal Survey, provided as Appendix D and the Consent Form, provided as appendix I.

The total estimate of burden is 1,633 hours. This burden calculation is an upper estimate, as it conservatively assumes that nobody will drop out of the field study after arrangements for participation have been made. The annualized cost is calculated using the 2018 median wage rate of \$18.58 per hour for 1,633 burden hours (Bureau of Labor Statistics, 2018) and is estimated to be \$30,347 without adjusting for the \$2 survey incentive and compensation for participating in the field study.

The sample size calculations that determined 400 field study participants were needed, recruited from among 4,400 completed postal survey respondents, were based on 2018 flight operations, before the COVID-19 pandemic. The sample size of 400 field study participants may need to be increased if the flight operations during the study is reduced by more than 30% compared to 2018 operations (see Part B.1.3, Table B-5). If flight operations are reduced by 40% or 50%, the sample size will need to be increased to 450 or 500 field study participants, respectively. The estimated respondent hour burden and financial burden in the case of these increased sample sizes is given in Table A-3.

Table A-1. Estimate of respondent hour burden, assuming a reduction in flight operations of 30% or less due to the Covid-19 pandemic

Respondent type and task	Number of respondents	Frequency of response	Average time per response: minutes (hours)	Total hour burden
Postal survey	4,400	1	8.25/60 (0.138)	605
Field study: Arranging for participation ¹	400	1	21.75/60 (0.363)	145
Field study: Morning survey	400	5	4/60 (0.067)	133
Field study: Characteristics questionnaire	400	1	15/60 (0.25)	100
Field study: Physiologic measurements ²	400	5	19.5/60 (0.325)	650
Total				1,633

Table A-2. Financial burden to respondents, unadjusted for financial compensation, assuming a reduction in flight operations of 30% or less

Type of Respondent	Number of respondents	Frequency of response	Average time per response (hours)	Hourly wage rate	Total respondent burden
Postal survey	4,400	1	0.138	\$18.58	\$11,241
Field study	400	1	2.57	\$18.58	\$19,106
Total					\$30,347

¹ Includes 3.0 minutes for telephone contact by the research team to confirm interest in and eligibility for the field study, and arranging to mail a consent form; and 3.75 minutes for telephone contact by the research team once consent is given, to arrange for scheduling of the study participation; and 15 minutes to pack up the study equipment at the end of the study period, attach the return shipping label, contact FedEx to schedule collection of the equipment, and put the package on the doorstep for collection.

² Includes 19.5 minutes to set up the noise recorder and heart rate monitor each night; attach the electrodes each night and remove them the following morning; and turn off the recording equipment at wake up.

Table A-3. Estimate of respondent hour burden and financial burden, assuming a sample size of 450 in the case of a 40% reduction in flight operations and a sample size of 500 in the case of a 50% reduction in flight operations.

Field study target sample size	Type of Respondent	Number of respondents	Frequency of response	Average time per response (hours)	Total hour burden	Hourly wage rate	Total financial burden
450 ^a	Postal survey	4,950	1	0.138	680.6	\$18.58	\$12,646
	Field study	450	1	2.57	1,156.8	\$18.58	\$21,494
	Total						\$34,140
500 ^b	Postal survey	5,500	1	0.138	756.2	\$18.58	\$14,051
	Field study	500	1	2.57	1285.4	\$18.58	\$23,882
	Total						\$37,933

^a Required only if flight operations are 40% lower than in 2018

^b Required only if flight operations are 50% lower than in 2018

13. Estimate of total annual costs to respondents.

The cost burden on respondents and record-keepers, other than burden hours, is zero.

14. Estimate of cost to the Federal government.

Based on the current National Sleep Study budget, the total cost to the Federal Government for the proposed survey from September 6, 2017 to June 30, 2023 is estimated to be \$4,363,938, part of which, \$1,177,644 is already awarded. In the event that a higher sample size is needed due to lower flight operations, the total cost to the Federal Government is estimated to be \$4,909,430 for a field study sample size of 450, or \$5,454,922 for a field study sample size of 500. These amounts include all direct and indirect costs of the design, data collection, analysis, and reporting phases of the study, as well as the production of public-use and restricted data sets. The

annual costs of Federal employees for monitoring the contract are estimated to be \$120,000 per year. These costs are based on 40 percent of the Project Officer's time, 10-15 percent of contract manager time to support ongoing data analysis and to coordinate and review the Study.

Averaging both the contractor costs and Federal staff costs over the expected 5 year 10 month study period the total average annual cost to the Federal government is \$868,104 per year.

15. Explanation of program changes or adjustments.

This is a new program.

16. Publication of results of data collection.

The product of this work will be summary data reports on the probability of being awoken by aircraft noise at different aircraft noise levels. Only statistical summaries of the information will be published, and no personally identifiable information will be disclosed. The analysis will be completed through a regression analysis for the dose-response data. See Supporting Statement B on details of dose-response regression. All data will be collected over a period of up to three years, with a planned start date of July 1st, 2020. The data analysis and drafting of the final report will be done through the twelve months following completion of the data collection.

17. Approval for not displaying the expiration date of OMB approval.

We are not seeking such approval. The data collection period is expected to last 2 years but may last up to 3 years.

18. Exceptions to certification statement.

There are no exceptions to the certification statement.

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