

## INSTRUCTIONS & TEMPLATE FOR GRANT PROPOSAL TRAINING & WORKSHOP SUBMISSION

This instruction is used for researchers interested in continuing to participate in the *2<sup>nd</sup> Series; Grant proposal writing training session*. After your submission via email to [ina-registry@kemkes.go.id](mailto:ina-registry@kemkes.go.id) (no later than May 17, 2023), the committee will decide if your concept plan is potential to be developed for grant proposal during the training period.

If you are selected for the *2<sup>nd</sup> Series; Grant proposal writing training session*, you may invite 2 people from your team to be involved in the grant proposal development and communicate intensively with INA-CRC and NIH team. You and your team will have the opportunity to increase your capacity and be trained by the grant specialists and experts in the clinical research field. If you are committed to completing your grant proposal and meet the deadline, you can continue to join the workshop session in the *3<sup>rd</sup> series; Grant proposal writing workshop session*. However, your concept plan will be evaluated by the trainers and mentors to be developed in the *3<sup>rd</sup> series workshop session*.

On the *3<sup>rd</sup> series* you will have face to face meetings with the mentors and develop your grant proposal with their assistance based on NIH grant requirements. To complete these series, we need your strong commitment during all the phases. However, there is no guarantee that your proposal will receive any NIH grant. The proposal reviewers will make the decisions independently. But hopefully, by the end of this workshop you will have ready submitted proposal to any funding institutions/grant.

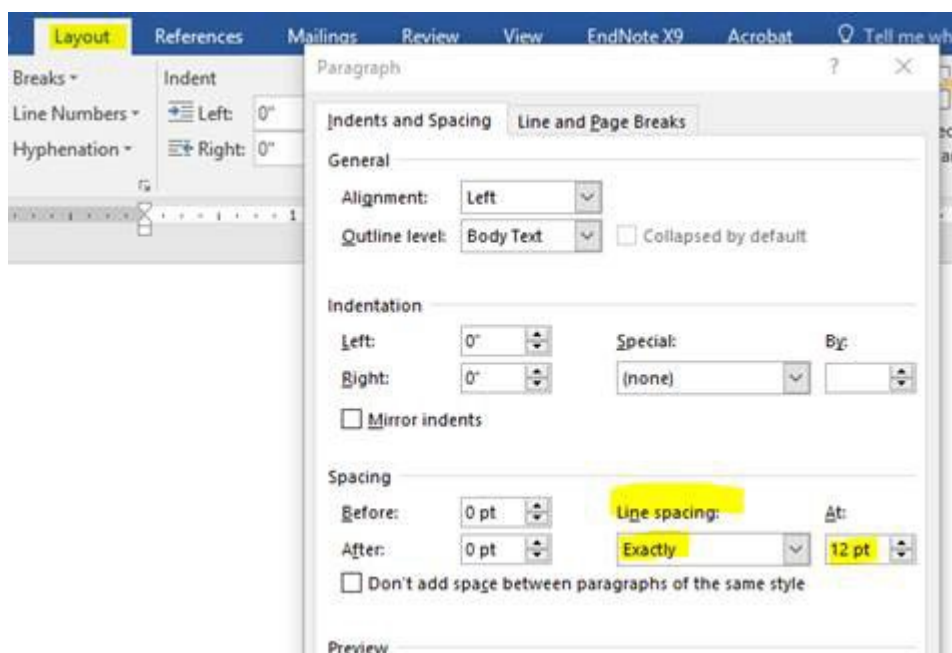
### A. DOCUMENT SETUP

For this submission we suggest using:

- A paper size no larger than standard letter paper size (8 ½" x 11")
- At least one-half inch margins (½") - top, bottom, left, and right - for all pages

#### Line Spacing

NIH requires that documents contain no more than six lines per vertical inch. To ensure there are no more than 6 lines per inch, you can set **line spacing in the document to "exactly 12 pt."** This can be done in the paragraph settings panel in Word's layout tab:



This works by setting each line in the document to take up 12 points of space. In typography settings there are 72 points per inch, so this sets the document to allow only 6 lines per inch. Once you've done that, you can double check the number of lines on a page by using the line numbers feature in

Word and set the display count to “restart each page.” This will display a line count per page in the far-left margin of the document. If everything is set correctly, you should find no more than 60 lines of text on each page per 8.5”x11” page with 0.5” margins.

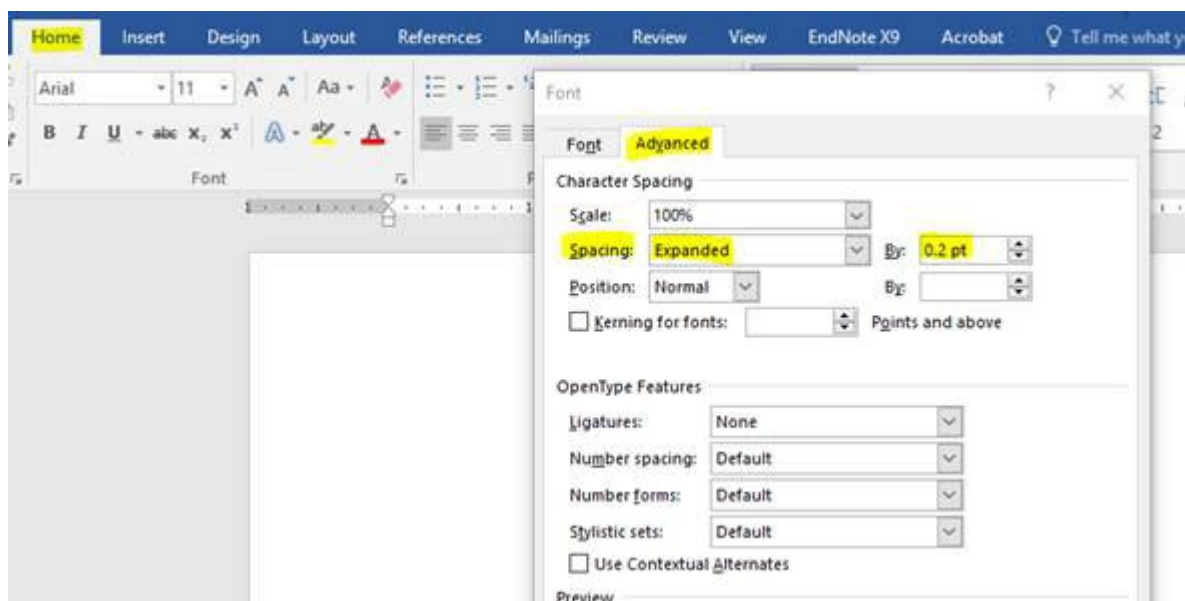
### **Font Size / Type Density**

NIH requires the use **of a font that is at least 11 pt in size** and generally recommends the use of either **Arial, Georgia, Helvetica, or Palatino Linotype**. However, they also go on to state that there must be no more than 15 characters per linear inch (including characters and spaces). On an 8.5”x11” page with 0.5” margins, this would mean **a maximum of 112 characters per line**.

We have found that in practice Arial 11 pt font, which most investigators use, does **not** always conform to the 15 characters per linear inch guidance. We have found that it most often seems to not conform when the document is set to use the justified alignment paragraph settings. That setting will sometimes contract text to the point where there are 120 characters or more per line.

With the other investigators who have experienced scrutiny from CSR, we found moving to Georgia font in 11.5 pt size made sure that the character count per line, including spaces, stayed just under 112 characters.

If you prefer to continue using Arial 11 as your font, we then recommend you update the advanced settings in font panel on Word’s home tab to the following:



The expanded spacing set to 0.2 pt allows for slightly more room between each character without being visually disruptive to the reader. This slight expansion seems to be enough to ensure that the character count per line, including spaces, stays just under 112 characters.

## **B. LANGUAGE**

All submission must be in English, but you should not worry to be perfect and grammatically correct in the beginning. However, you need to ensure that you express the ideas clearly in the concept plan.

## **C. DETAILS OF CONCEPT PLAN**

After the title of concept plan, we will have two main sections: Specific aims and Principal Investigator biodata.

## Title

*The title should be short and descriptive of the proposed research.*

## Example

The Impact of Insomnia on Pain, Physical Function, and Inflammation in HIV.

## Specific Aims

*A strong proposal is driven by a strong hypothesis(es) that leads to clear research objectives. The Specific Aims section should encapsulate these concepts. It typically begins with a brief narrative paragraph or two that concisely states the introduction, issue, or problem to be addressed, describes the long-term goals or objectives of the project, and clearly states the hypothesis to be tested. This is followed by a numbered list of the Specific Aims. The aims test different aspects of the hypotheses, operationalize the objectives and provide a rationale for the experimental approach to be described later. For clarity, each aim should consist of only one sentence. Use a brief paragraph under each aim if detail is needed. **Most successful applications have 2-4 specific aims.** Make sure the aims are logical, achievable, and clearly relate back to the hypothesis. Depending on the goals of the application, the Specific Aims section may take on a somewhat different form if, rather than testing a specific hypothesis, the goal is to create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. In crafting the Specific Aims section, you should consider the following questions.*

- Do your specific aims address the research goals and objectives?*
- Did you state your hypotheses and link them appropriately to your specific aims?*
- Are the specific aims clearly related to each other?*
- Do the specific aims represent an achievable amount of work?*

*An unrealistic and overly ambitious set of specific aims is a common pitfall of many applications. This section is limited to one page.*

## Example:

Insomnia is a common and debilitating sleep disorder in persons living with HIV (PLWH), with prevalence estimates ranging from 30-73%, which is higher than in the general adult population (~20%). Insomnia is increasingly viewed as a risk factor for the onset and/or worsening of pain and physical disability. This is particularly relevant for PLWH because estimates of chronic pain development in HIV range from 54-83%. Inflammatory processes represent an important biologic mechanism linking insomnia to pain and poor physical functioning. Insomnia promotes systemic inflammation as well as inflammatory reactivity to physical stressors like pain. There is growing agreement that inflammation can substantially exacerbate pain symptoms in everyday life, as well as increase sensitivity to painful stimuli in the laboratory setting. Furthermore, insomnia burden can vary substantially from week to week, and this variation tends to map on to variations in inflammation, pain severity, and physical functioning over time. Taken together, insomnia may be a significant driver of pain and poor physical functioning in PLWH through the proliferation of inflammatory mediators.

The overall objective of this application is to investigate the impact of insomnia on pain, physical functioning, and inflammation in PLWH. Our central hypothesis is that insomnia promotes pain symptoms and sensitivity, poor physical functioning, as well as systemic and pain-evoked inflammation in PLWH. This hypothesis is generated from both contemporary literatures, and our own preliminary data. In 2017, we conducted a pilot study that examined associations among self-reported insomnia burden, perceived physical disability, inflammation, and pain sensitivity in PLWH using resources provided by the University of Alabama at Birmingham's Center for AIDS Research. We found trends in our data suggesting that insomnia may be associated with enhanced pain sensitivity and greater reactivity of IL-6 and TNF-alpha to painful stimulation, as well as greater perceived physical disability. We now propose a larger, adequately powered study to confirm these preliminary findings.

Specific Aim 1: To determine whether insomnia promotes increased sensitivity and inflammatory reactivity to pain stimuli in PLWH. This aim will be addressed in the laboratory following completion of structured interviews for sleep disorders, home (ambulatory) sleep monitoring with actigraphy, and

validated daily sleep diaries/questionnaires in order to identify PLWH with and without insomnia according to DSM-5 diagnostic criteria. To increase rigor of study design, comparison groups of non-HIV individuals with and without insomnia will also be included. Participants will complete a standardized battery of experimental pain stimuli designed to assess pain sensitivity. Blood will be drawn before, during, and after the painful stimuli to examine pain-evoked inflammatory responses.

- Hypothesis 1a: PLWH with insomnia will have significantly increased pain sensitivity (e.g., ↓pain threshold, ↓pain tolerance) compared to PLWH without insomnia and the non-HIV groups with and without insomnia.
- Hypothesis 1b: PLWH with insomnia will demonstrate exaggerated pro-inflammatory reactivity and suppressed anti-inflammatory reactivity to the pain stimuli in comparison to PLWH without insomnia as well as the non-HIV groups with and without insomnia; inflammation and pain sensitivity will be correlated.

Specific Aim 2: To determine if weekly fluctuations in insomnia burden drive changes in inflammation, pain severity, and physical functioning in PLWH. This aim will be carried out by having the PLWH with insomnia identified in aim 1 and the non-HIV insomnia group wear ambulatory sleep monitoring devices (i.e., actigraphy) and complete daily sleep and pain diaries. Sleep monitoring and daily diaries will be completed for 7 consecutive days, after which blood will be drawn to evaluate inflammatory markers. Participants will then complete a standardized physical function battery. These procedures will be completed at the same time every week over the course of 6 consecutive weeks. Inflammatory markers, pain, and physical functioning following weeks of high insomnia burden will be compared to those following weeks of low insomnia burden.

- Hypothesis 2a: Insomnia burden, inflammation, pain severity, and physical function will be significantly worse across the six weeks for PLWH with insomnia compared to the non-HIV with insomnia group.
- Hypothesis 2b: Pro-inflammatory markers will be significantly elevated, and pain severity and physical functioning will be significantly worse, following weeks of high insomnia burden in comparison to weeks of low insomnia burden, particularly for PLWH.
- Hypothesis 2c: Insomnia-related weekly variability in inflammatory markers will significantly correlate with weekly variability in pain severity and physical functioning.

If our hypotheses are confirmed, we will identify: 1) insomnia as a major driver of pain and physical functioning in PLWH, and 2) inflammation as an important insomnia-related mediator of pain in PLWH. This research could help confirm insomnia as a therapeutic target for the suppression of pain and inflammation in PLWH. This proposal addresses a high/medium priority topic of research (health comorbidity linked to HIV) according to NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding (NOT-OD-15-137).

#### **Principal Investigator Biodata**

Name	:
Email	:
WhatsApp number	:
Institution	:
Research Experience in the past 3 years	:
Publication	: