**Template for an Intention Letter. Regular extension 1 to 2 pages.**

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1. What is the Problem that you are going to study?

Justify the proposed research: Provide a background of the PROBLEM and its significance for at risk-populations. Explain what you know and what has been done related to the problem.

For example: *In Venezuela, mortality for cardiovascular disease (CVD) was responsible for 30.5% of all deaths, increasing by 8.3% since 2007 to 2017. The prevalence of cardiometabolic risk factors in the country is also increasing. The prevalence hypertension increased from 30.0% to 34.1%, metabolic syndrome from 35.7% to 42.2%, diabetes from 8.0% to 12.3%, and prediabetes from 14.4% to 34.9%. Prediabetes increased 242% in a decade, from 2.4 to 7 million of adults, estimating that 1.7 million of adults could advance to type 2 diabetes (T2D) in the next 3 to 5 years.*

*The American Diabetes Association (ADA) recommends implementing the Diabetes Prevention Program (DPP) in subjects with prediabetes.*

1. What is the Gap?

Gaps are the specific barriers to progress—and the motive and focus of entire project. Need to be clear and explicit, and located in the right place, at end of ‘known’ and just before ‘response’ (Aims). This is the justification of your research work. Each gap exposed justify each aim.

*For example: DPP has consistently proved to reduce T2D incidence by 58%, with long term benefits.* ***However****, to translate this effectiveness to primary care settings is a major challenge. A meta-analysis of 36 pragmatic clinical trials of diabetes prevention programs in primary care settings showed a reduction in T2D incidence by 26%, less than half than the original studies (58%). In these studies, Lifestyle Interventions (LSI) only showed a pooled mean weight loss 1.57 kg higher than standard care, demonstrating the large difficulties to reduce the weight of participants at the community level.*

*The effectiveness of intervention including an initial rapid weight loss in primary care levels in Venezuela is unknown.*

1. Which are the aims?

The aim should be focused on answering the gap that you expressed before. It should be **one aim for each gap**, it should not be more than three. Describe the aim using actives verbs (describe, assess, quantify). Aims should be SMART: Specific, Measurable, Achievable, Relevant, Time-bound. Aims need to be independent.

*For example:* To compare the weight loss achieved with two LSI programs in a community health center of Venezuela: a) A hybrid LSI including rapid weight loss with total diet replacement (TDR), followed by medical nutrition therapy (MNT), and the DPP protocol, vs b) only the DPP.

1. What is your hypothesis?

If it is relevant and if you are measuring a hypothesis, this should be included. Be as accurate as possible with your hypothesis.

*For example:* *Patients using the treatment A will reduce their weight 30% more that those patients using the treatment B.*

1. What is the result that you will get from your study (**outcome**)?

Here you must indicate which is the product that your study will throw.

*For example:* *the change of weight.*

1. What are the exposures to which your result is subject (**exposure**)?

Here you must point out the factors that influence the outcome.

*For example: treatment A and treatment B.*

1. What is the potential impact of this project?

If you have success, how your outcome will impact on the gap. Explain the impact of each outcome.

*For example: If this outcome is achieved, it will have an enormous impact in the way that the DPP should be provided in the primary health care systems in developing countries, increasing the effectiveness of weight reduction, and in consequence, improving cardiovascular health and diabetes prevention.*

**Methods**

1. What is your study design?
2. Where will you get the study population?

Indicate whether the study population is going to be selected from a hospital, from a school, from a consultation, from the community, etc.

1. What are the criteria to include study participants?

Detail what criteria should fulfill a subject per study entry.

For example: *people with 20 or more years who have a body mass index of 25 or more.*

1. What are the criteria to exclude participants after they were included?

Indicate in detail what criteria a subject must meet so that he cannot participate in the study after he has already met the inclusion criteria.

For example: *subjects with cancer or receiving chemotherapy.*

1. What will the sampling be like to select the subjects?

Define whether participants will be selected at random (random) or convenient sampling. Try to make your study random, it gives more power to the results because it eliminates selection bias and makes the results representative of the study population. Choose one of the random methods:

a) Simple random sampling: every subject has the same probability of participating

b) Stratified random sampling: the sample is divided by strata or categories

c) Random sampling by clusters: the sample is divided into clusters or groups

d) Stratified and cluster random sampling.

If it cannot be random, you can choose them for convenience, for example:

a) Sampling in SNOW Balling

1. Who are the research team?

Briefly identify research team members and specific roles, as appropriate. Demonstrate that they have the knowledge, skills, and experience to bring the project to a successful conclusion.