

Help Sheet for Writing Specific Aims

The specific aims for your study can be summed up in four neat paragraphs. Each paragraph will contain concise and pertinent information for your study. Remember to keep it simple, relevant, and keep the reader moving smoothly through your thought process.

Here are your four basic paragraphs:

Make sure that you attend to each of the bulleted items in a thoughtful and effective manner. Please note that if you are exceptional with words and your ideas, you can easily create a condensed version of this format; this outline is meant to provide very basic insight into writing an award-winning specific aims section for your clinical trial protocol.

1. Introductory Paragraph

- *Opening sentence* contains around 3-4 extremely creative thoughts. This will grab the attention of your reader.
- State what is *known* about this issue.
- State what is *unknown* about this issue.
- State why is this lack of knowledge important, i.e., how it prevents the vertical propulsion of this field of medicine.

2. What, Why Whom Paragraph

- State the overall, long-term goal of your mission. This represents any future projections or the continuum of your line of research.
- State the overall objective of this application. This is a step to achieving your long term goal.
- Steps along the continuum for this research that must be achieved, regardless of how hypothesis tests.
- Clearly state your central hypothesis. All vague and unfocused fishing expeditions for information will not adequately fulfill your research mission and appears as an invalid study design.
- State your rationale for your hypothesis, or how did you come up with the central hypothesis.
- Briefly explain why your research design and team investigators are the best possible solution for the topic at hand.

3. Specifics Paragraph

(Briefly detail your specific aims that will test your central hypothesis, citing primary and secondary endpoints.)

4. Payoff paragraph

- Briefly explain why this application is innovative
- State your expected outcomes, or what you expect to find at the conclusion of the study.
- And equally as important to the former pieces of the specific aims section: state plainly and simply the general positive impact that your study will have on the populace at large. In other

words, why should we care, why should you get funding, and what is the payback for your work?

Here is an example of a Specific Aims section:

A. Specific Aims

Polycystic Ovarian Syndrome (PCOS) is a common and significant health problem, affecting 4-6% percent of reproductive aged women [1, 2]. Irregular menses, anovulation, infertility, androgen excess, hirsutism, obesity, acne, excessive skin pigmentation, and hyperinsulinemia all characterize this complicated syndrome. Consequently, the majority of women with PCOS are infertile. In order to conceive, many must seek infertility treatments which are costly, time consuming, and emotionally demanding for them, their partners, and family. Insulin resistance and hyperinsulinemia have been shown to effect ovarian and adrenal steroidal metabolism contributing to the endocrine disorders associated with PCOS [3-5]. These findings have spurred the development of therapeutic strategies to reduce PCOS related hyperinsulinemia. Several studies have demonstrated the efficacy of insulin-sensitizing compounds such as Metformin in reducing PCOS-associated hyperinsulinemia and diminishing endocrine and metabolic abnormalities found in women with PCOS [6-9]. This improvement in endocrine function often results in better menstrual cycle regularity[10]. It has been proposed that *Gymnema sylvestra*, an insulin-sensitizing agent[11] commonly used in Ayurvedic medicine, could be used as an alternative to Metformin in PCOS. Animal studies have shown the hypoglycemic effect of *Gymnema s.*[12-14]. Other effects of *Gymnema s.* shown in diabetic rat and rabbit models include regeneration of pancreatic islet cells, decreases in blood sugar, and increases in serum insulin[15, 16]. Although the mechanisms of *Gymnema s.* remain unknown, they may include: increase in glucose uptake and utilization by cells, increase in insulin release through cell permeability[16], increase in β -cell number, and stimulation of β -cell function[17]. *Gymnema s.* has not yet been studied in women with PCOS.

The primary goal of this study is to evaluate the feasibility of studying *Gymnemas.* as a natural treatment for PCOS. This will be done through the examination of recruitment yields, retention rates, and measures of compliance.

The secondary goal of this feasibility study is to examine *Gymnema s.* as a possible natural treatment for women with PCOS. This will be examined through changes in menstrual cycles, free testosterone, LH/FSH ratio, insulin resistance, SHGB, HgA1c, estradiol, progesterone, cortisol, and hirsutism. Studies have shown that Metformin modulates and restores menstrual cycle regularity in women with PCOS. Because *Gymnema s.* has blood sugar regulation properties similar to Metformin, we would expect *Gymnema s.* to have similar effect on cyclicity as Metformin.

Specific Aim 1: To determine the feasibility of recruiting, enrolling, treating, and following women with PCOS, who are being treated with *Gymnema s.* or placebo for 6-months.

Hypothesis: This protocol will be suitable for a larger randomized-controlled study of the efficacy of *Gymnema s.* in women with PCOS.

Specific Aim 2: To compare at baseline, and months 2, 4, and 6 of intervention, parameters of menstrual cycle regularity for 6-months, between women taking *Gymnema s.* vs. placebo.

Hypothesis: *Gymnema s.* will have an effect on menstrual cycle regularity in women with PCOS.

Specific Aim 3: To examine hirsutism, free testosterone, FSH/LH ratio, fasting glucose, insulin, SHBG, HgA1c, estradiol, progesterone, and cortisol, in women taking *Gymnema s.* vs. placebo for 6-months.

Hypothesis: There will be a difference in clinical and endocrine characteristics (including hirsutism, free testosterone, FSH/LH ratio, fasting glucose, fasting insulin, SHBG, HgA1c, estradiol, progesterone, and cortisol) between women treated with *Gymnema s.* vs. placebo.

Specific Aim 4: To examine over 6-months, changes in quality-of-life and emotional well-being in women with PCOS taking *Gymnema s.* or placebo.

Hypothesis: Treatment with *Gymnema s.* will have an effect on health related quality-of-life and emotional well-being.