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OF THE REQUIREMENT FOR THE DEGREE

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IN
NURSING

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THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN
PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF
MASTER OF SCIENCE IN NURSING.

Susan Andera
PROJECT COMMITTEE CHAIR

4-23-2021

DATE

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4-23-2021

DATE
Adjunct Therapy of Growth Hormone in Controlled Ovarian Hyperstimulation

A Grant Proposal

Presented to the faculty of the School of Nursing

California State University, San Marcos

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Nursing

Family Nurse Practitioner

by

Danielle Miller, MSNc, RN

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ABSTRACT

Adjunct Therapy of Growth Hormone in Controlled Ovarian Hyperstimulation

By

Danielle Miller

Statement of Problem

Infertility affects approximately 12% of the population worldwide. Infertility can cause major social and emotional disorders. Currently there is a lack of agreement in the ideal treatment of infertile women. This grant proposal intends to study the effect of adding human growth hormone using a retrospective observational case control study. The dependent variable being examined is mature oocytes produced during a controlled ovarian hyperstimulation cycle. The study is significant to advanced practice nursing by gaining information on adjunct treatments to properly educate infertility patients about treatment options as well as supporting the couple emotionally through the fertility process.
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CHAPTER ONE: INTRODUCTION

Management of patients with poor ovarian response is controversial. At present there is no consensus on how to treat these patients or the ideal protocol; a single treatment strategy has not been proven to be superior at this time. A number of approaches have been used to try and improve oocyte yield, such as increasing or decreasing the dose of gonadotropin, estrogen priming, testosterone gel, using different types of gonadotropin releasing hormone antagonists to prevent over suppression, and the use of growth hormone (GH). Protocols are constantly evolving to attempt to decrease the amount of gonadotropin needed, improve follicular response, and the ultimate goal of increasing live birth rates. Previous studies have researched the adjunct therapy of GH added to different types of controlled ovarian hyperstimulation (COH) regimens that include human menopausal gonadotropins (hMG), gonadotropins and gonadotropin antagonist with mixed outcomes. This study was designed to determine if there is a correlation between the adjunct therapy of GH in poor responders and the number of mature oocytes produced.

The rationale for adding GH is to increase the number of mature oocytes retrieved, this is based on both human and animal data. Growth hormone directly or indirectly effects every organ in the body (Silva, Figueiredo, & Hurk, 2008). Evidence supports that GH regulates folliculogenesis in the ovary. GH has a number of effects on the ovary which involves a favorable impact on both steroidogenesis, follicular growth and oocyte maturation. Growth hormone effects follicular development in a number of ways; improving growth of small follicles by preventing atresia and later on in the follicular phase by augmenting folliculogenesis, luteinization and steroidogenesis (Bachelot et. al., 2002). This study will focus on the improvement in the number of mature oocytes produced.
Background and Significance

Infertile patients with poor ovarian response can be a difficult population to manage in assisted reproductive technologies. Numerous types of controlled ovarian hyperstimulation protocols have been utilized in an attempt to optimize follicular response but an ideal protocol has not been established. The optimal stimulation protocol for poor responders continues to be a debate amongst providers. Beyond trying to adjust gonadotropin protocols a variety of adjunct therapies have been tried, including GH, pyridostigmine, oral L-arginine, transdermal testosterone, and letrozole.

Growth hormone is a pituitary peptide that stimulates proliferation and differentiation of granulosa cells, as well as increasing estradiol production in ovaries (Dunne, Seethram & Roberts, 2015). Dunne et al (2015), reports that GH plays a role in folliculogenesis. Growth hormone can act both directly and indirectly by producing insulin-like growth factor one (IGF-1) and plays a role in oocyte maturation by increasing the ovaries sensitivity to gonadotropin, as well as enhancing follicular development (Dakhly, et. Al, 2015). Although a number of studies have looked at the benefit of GH, the study results have been mixed, some finding improvements in mature eggs and pregnancy outcomes, while some have failed to find a benefit. Study conclusions suggest that more studies are needed to determine whether the use of GH supplementation improves outcomes.

Significance to Nursing

1 in 8 couples have trouble achieving pregnancy or sustaining a pregnancy (CDC, 2019). Infertility can result in major emotional, social and mental disorders, including decreased satisfaction with partners and overall quality of life (Masoumi et al., 2016). The Advanced Practice Nurse’s (APN) role is to help the patient wade through medical terminology, medication instructions, and side effects while supporting the patient in achieving the goal of
having a family. For the patient, acknowledging the fact one is infertile can lead to a loss of self-
esteeem and a loss of control which can interrupt the patients professional, person and social
goals. All of this intensifies the need to view the infertility experience holistically and to
integrate the psychological and medical dimensions. The impact on the APN’s practice of
gaining this information is to help educate patients about different types of fertility treatment, as
well as emotional support for the couple.

**The Problem**

Controlled ovarian hyperstimulation (COH) is used in women to elicit a multi-follicular
response and by doing so boosts the chances of producing more than one mature oocyte. In
women with poor response to COH many options have been explored to help improve cycle
outcomes. Growth Hormone supplementation has been studied as one of the adjunct therapies in
women undergoing COH with mixed results.

**Purpose of the Research**

The purpose of this study is to see if there is a correlation between human growth
hormone supplementation during a controlled ovarian hyperstimulation cycle and the number of
mature oocytes yielded at one of the largest fertility centers in San Diego.

**Research Question**

The research question is “does the adjunct therapy of growth hormone (independent
variable) during a controlled ovarian hyperstimulation cycle increase the number of mature
oocytes collected (dependent variable)?” The null hypothesis states that the number of mature
oocytes collected (dependent variable) will remain unchanged with the use of human growth
hormone supplementation (independent variable) during a COH cycle. The alternative
hypothesis states there will be a difference in the mature oocytes retrieved (dependent variable)
and the use of growth hormone supplementation (dependent variable) during a COH cycle.
Research Variables

The dependent variable in the study is the number of mature oocytes produced. Mature eggs are Metaphase II (MII) eggs. They are identified as having extruded a single polar body into the perivitelline space and the zona pellucida. The independent variable is the use of growth hormone supplementation by subcutaneous injection daily throughout a controlled ovarian hyperstimulation cycle.

CHAPTER TWO: LITERATURE REVIEW

The database used for this search was CINAHL, PubMed, and Google Scholar. Literature search terms included human growth hormone, growth hormone, in vitro fertilization, controlled ovarian hyperstimulation, ovulation induction, poor responders, and adjunct therapies. The search was limited to English, with a wide range of articles and the earliest dating from 2009. The researcher focused on articles that included growth hormone therapy during a controlled ovarian hyperstimulation cycle, although some were found using GH in the luteal phase prior to the COH cycle as well.

A study conducted by Bayoumi, Dakhly, Bassiouny and Hashish (2014) assessed the efficacy of adding GH to the microflare protocol among women (n=72) with poor ovarian response. The study was a parallel open label, randomized control trial that looked at two groups of women that were undergoing a microflare stimulation protocol. The women were randomly assigned to either the GH group or the group without GH. The study looked at the mean number of mature oocytes collected and the mean number of fertilized oocytes. The study ultimately found that supplemental GH to the microflare protocol lead to some potential benefit to women with poor ovarian response. The study concluded that further studies were necessary before recommending routine clinical use.
A similar study was performed by Dakhly et al., (2018), who looked at the adjunct therapy of GH in a long down regulation protocol on the outcomes of in vitro fertilization cycles in poor responders. Similar to the previous study, this was a randomized control trial looking at female poor responders (n=240) undergoing a long down regulation protocol, one group with the addition of GH and the other without. The main outcome measure was live birth rates. The study concluded that GH supplementation improved the number of oocytes collected, mature oocytes, fertilized oocytes, transferred embryos and cryopreserved embryos. However, there was no significant difference in live birth rates. The study concluded that further studies are needed to know the true impact of co-treatment with GH to induction protocols. The study reported that there was no difference in live birth rates amongst the two groups, suggesting no benefit from the adjunct therapy of GH.

In 2016, Du, Yang, Li, Hao and Guo published a retrospective clinical trial (n=1142) that involved patients who had a normal response to high dose gonadotropin treatment. The study group (n=556) was given a daily injection of GH starting the same day as the gonadotropin treatment and lasting for 5 days. The participants were then further divided into subgroups: age greater than 35 and age less than 35. The study focused on in vitro fertilization and embryo transfer outcomes. The implantation rates and pregnancy rates were significantly higher in the study group. The analysis used a multivariate logistics regression model to predict that GH group was a significant factor in predicting pregnancy outcomes. The study found that co-treatment with GH in a long agonist protocol in patients who responded normally while undergoing treatment could increase both implantation and pregnancy rates. The study did not find a significant difference in the number of mature oocytes between groups.

Eftekhar, Aflatoonian, Mohammadian, and Eftekhar (2013) conducted a randomized controlled trial to assess cycle outcomes after supplementation of growth hormone in an
antagonist protocol in poor responders. The participants were randomly assigned to two groups; group I (n=40) received GH in addition to gonadotropin and antagonist protocol, while group II (n=42) received only gonadotropin and antagonist protocol. The study concluded that the number of oocytes retrieved was significantly higher in group I, as well as the number of embryos. The study found no significant differences between the two groups in regard to implantation, chemical and clinical pregnancy rates.

Another study conducted by Ho et al., (2017) investigated the effects of GH co-treatment in ovarian stimulation in three types of infertile women of advanced maternal age, poor responders, and previous in vitro fertilization failure patients. The study was a retrospective observational study (n=436) of women undergoing GH co-treatment in ovarian stimulation. The main measure outcomes were the number of oocytes and embryos, quality of embryos and implantation and pregnancy rates. The study concluded that in infertile women of advanced age, GH showed no statistical difference in number of oocytes and embryos, quality of embryos and rates of implantation and pregnancy. The women with GH adjuvant therapy for patients with one or more failed IVF cycles and for poor responders significantly improved both oocytes and embryo numbers, as well as implantation and pregnancy success rates.

Keane, Yovich, Hamidi, Hinchliffe and Dhaliwal (2017) completed a retrospective analysis of 400 women. The purpose of the study was to evaluate the benefit of growth hormone supplementation in poor prognosis women undergoing fresh IVF transfer. The study concluded that the addition of GH increases live birth rates, particularly in younger women. It also concluded that the number of embryos in the GH group have better implantation potential.

Homburg, Singh, Bhide, Shah and Gudi (2012) examined the literature studying the use of growth hormone in fertility treatment. The design was a systematic review that included several studies. The conclusion of this review was that although an answer needs to be found for
the treatment of poor responders, there is yet to be any concrete evidence that supports the addition of GH as part of the routine regimen in treating this difficult population of poor responders.

**Major Variables Defined**

**Demographics Variables.** Demographic variables are defined as follows; age refers to the chronological age of subject; race, belonging to a racial division or group, to include Asian, Black, Caucasian (non-hispanic), Hispanic, and Native American. BMI is defined as a person’s weight in kilograms divided by the square of the height in meters.

**Research Variable.** One key observational variable was poor responders, who are the population of patients receiving this type of treatment. For the purpose of this study poor responders were defined as patients with less than three oocytes retrieved, previously cancelled cycles due to poor response, low ovarian reserve (antral follicle count <5-7 or anti-Mullerian hormone <0.5-1.1 ng/ml) (Dakhly, Bassiouny, Bayoumi, Hassan, Gouda & Hassan, 2018). The Independent variable is growth hormone, subcutaneously administered at a dose of 2.9IU for a minimum of eight days during controlled ovarian hyperstimulation. The Dependent variable is mature oocytes.

**Physiologic and Theoretical Framework**

Reproductive function in the female relies significantly on the role of Growth hormone. Growth hormone from the pituitary stimulates production of hepatic IGF-1. Pituitary GH and IGF-1 work together to stimulate ovarian, uterine, mammary and oviduct function. (Harvey & Hull, 2001). The mammary gland, placenta, ovary and oviduct also produce GH that could potentially act directly and locally on IGF-1 to affect reproductive function (see Appendix
A for effects). Both pituitary GH and hepatic IGF-1 are involved in routine maintenance of ovarian function (Hull & Harvey, 2001).

The ovarian function effects of growth hormone affect both folliculogenesis and steroidogenesis. Spiliotis (2003) states that both the growth hormone receptor mRNA and protein are present in ovarian cells, and growth hormone’s direct action is imperative for regulating both gonadotropin-dependent and independent functions. Growth hormone releasing hormone and it’s receptors are also found to be present in ovarian tissue, together with insulin-like growth factor, somatostatin and somatostatin receptors. These elements play a key role at the local ovarian function level likely by making small but important adjustments at the cellular level (Moretti, Bagnato, Salon, & Catt, 1990). Growth hormone that originates from the pituitary and ovary promotes gametogenesis by binding to GH-receptor on the thecal, granulosa and luteal cells (Spiliotis, 2003).

Normal development of follicles and oocytes is essential for production of viable gametes and necessary steroid production. Growth hormone plays a promotional role in fertility by affecting the maturation of the follicles and gametes (Gong, Mcbride, Bramley, & Webb1993). The importance of the GH role is found early in follicle-stimulatiing hormone independent follicular development because GH-binding reaches a peak during early folliculogenesis. GH is found to have an integral role in follicle recruitment and the initiation of oocyte growth as well as stimulating growth and atresia of small follicles (Hull & Harvey, 2001).

Growth Hormone secretion is related to age (Du, Yang, Li, Hao & Guo, 2016). The secretion of GH decreases post-adolescence. Deficiency in GH can play havoc on ovarian function and lead to reproductive difficulties (Spiliotis, 2003). GH is a key player in ovarian
function, while working in conjunction with gonadotropins. The normal function of the ovary is impeded in growth hormone deficiency causing disruptions in female reproductive ability (Spiliotis, 2003).

The theoretical framework for this study is based off Maslow’s Hierarchy of Needs model. This study addresses the nurse practitioner’s supportive role while helping clients through the fertility process and to hopefully meet each need and achieve wholeness. This model is based on a theory that each level of need, must be achieved before moving on to the next (Maslow’s Theory of Needs, 2021). While the study will look at outcomes using adjunct treatment, one of the nurse practitioner roles is to assist the patient in meeting these needs.

Maslow’s Hierarchy of needs includes, physiological, safety, belongingness, esteem, and self-actualization (see appendix B for Hierarchy of Needs). While trying to guide the patient through uniquely tailored fertility treatment is the job of the nurse practitioner to ensure the needs of the patient are met not just medically but mentally. The nurse practitioner will be focusing on the levels of belongingness and esteem. Guiding the patients through their treatment while ensuring the patient finds a sense of belongingness with secure relationships and support systems including family and friends. (Maslow’s Theory of Needs, 2021). According to Maslow’s Hierarchy of Needs (2020), the nurse practitioner is also supporting the patient to achieve their goals of having a family. Alternatively, should the patient not be able to achieve a family, it becomes even more important to help the patient avoid feeling of isolation and highlight the loving relationships the patient has, family and friends, for support.

Summary

Growth hormone plays a vital role in the female reproductive system. GH, both from ovarian and pituitary origin play a regulatory role folliculogenesis and steroidogenesis. It also
has a function in the signals between both oocyte and granulosa cells. Growth hormone, in conjunction with gonadotropins, are an integral part of ovarian function.

The review of the literature illustrates that the study outcomes are mixed. However, a number of articles concluded that growth hormone has a positive effect on cycle outcomes, including increases in number of mature oocytes retrieved and live birth rates. The majority of studies reported their limitation as small sample size and population. Almost all of the studies and reviews found suggest that more studies are needed to confirm the effectiveness of growth hormone supplementation during controlled ovarian hyperstimulation cycles.
CHAPTER THREE: METHODOLOGY

A number of studies have been conducted to show the effects of growth hormone on a number of variables on the reproductive patient. The majority of the studies report discrepancies in the results among the studies and recommend further research. In agreement with the literature review, further studies need to be conducted. This chapter will analyze the research design, sample size and bias.

Research Question

“Is there a correlation between the adjunct therapy of growth hormone during a controlled ovarian hyperstimulation cycle and the number of mature oocytes collected?”

Research Design

A retrospective, case control study will be completed for this study with the purpose to analyze the correlation between supplemental growth hormone during COH cycles and the number of mature oocytes collected. Chart review will be completed to collect data on patients undergoing two similar cycles, one while taking growth hormone and the other without. The number of mature oocytes (MII) collected will be analyzed.

Population and Sample Size

A single-center, retrospective study will be conducted on female patients to explore the efficacy of adding growth hormone to gonadotropins from the largest fertility center in San Diego, California. The study focused on female patients under the age of 43 with a BMI over 18 and under 35 who have undergone two controlled ovarian hyperstimulation cycles. One cycle with the adjuvant growth hormone therapy and a similar cycle without growth hormone. A purposive sampling process will be used to ensure heterogeneity of the sample selected in terms of age, ethnicity, and protocol types.
**Inclusion and Exclusion Criteria.** The inclusion criteria will be as follows: clinic patient, female, ages 25 to 40, patients undergoing 2 similar cycle types the first cycle without growth hormone and the second cycle with growth hormone. The exclusion criteria for study participants will include patients undergoing only one cycle, cancelled cycle, use of additional adjunct treatment, such as dexamethasone or letrozole, patients undergoing mini stimulation protocol which the goal is usually 1-2 mature oocytes. Finally, patients with a BMI under 18 or over 35 will be excluded from the study.

**Sample Size.** The sample sized required was determined using a moderate effect size of 0.3 and found to be 12 patients who had undergone two cycles selected from current or previous patients of the fertility center to achieve a power of 0.80 (Faul, 2014). The calculated sample size (n=12) was obtained by using G-Power (see Appendix C for g-power graph). A t-test family was used, and a two tailed t-test model was chosen from G-Power to analyze the difference between the two means (Faul, 2014). The literature review aided in calculating the sample size of 12 and an alpha level of 0.5 has been calculated (Bayoumi, Dakhly, Bassiouny &Hashish, 2015).

**Measurement Methods**

Careful review of medical records will be completed to identify a subset of patients who had undergone two similar controlled ovarian hyperstimulation cycles as patients will be acting as their own controls for each treatment group. The two groups are a treatment group with growth hormone supplementation and the other without. The treatment group without GH will be labeled the control group. In this group, all patients would have received the standard of care without the addition of growth hormone. In the second, experimental group, the patients would have received the standard treatment plus GH in the form of Saizen or Omnitrope that was administered subcutaneously beginning the day of follicle stimulating hormone and continued
until at least day eight of stimulation at a dose of 2.9 mg per day. The standard of care for
therapy included stimulation with follicle stimulating hormone using specific dosages given by
their physician and in most cases an antagonist or micro-dose Lupron protocol. Ovulation was
triggered using with human chorionic gonadotropin (Ovidrel). Transvaginal aspiration was
completed 36 hours post-trigger under intravenous sedation. Embryology data sheets will be
reviewed to find the number of mature oocytes that were retrieved for each cycle. The main
clinical outcome is the mean number of mature oocytes (MII) retrieved. Data Collection Process

**Data Collection and Analysis**

Data will be collected by chart review on the number of patients that time allows keeping
in consideration the sample size required to power the study. Once patients are selected, lab data
from the charts will then be reviewed to observe the outcomes of each cycle. Subject results will
be examined for both groups, an experimental group where they received growth hormone (1)
and the control group with no adjuvant growth hormone treatment (2) as each subject will be
used as their own control.

**Coding.** The study includes two categories the independent variable which is human
growth hormone and will be coded as growth hormone and those cycles without growth
hormone, coded as no growth hormone. The independent variable is nominal. The dependent
variable, which is a ratio value, the number of mature oocytes collected. For demographic data,
Race/Ethnicity will be coded at 0 = Asian, 1 = Black, 2 = Caucasian (non-Hispanic), 3 =
Hispanic and 4 = Native American and is nominal. Age is a ratio measurement and finally BMI
will be recorded which is also a ratio variable.

**Data Analysis.** Once all data was collected, it will be entered into Statistical Package for
the Social Science (SPSS). Analysis will be completed per protocol. Data to be summarized using
the mean and standard deviation for quantitative variables. Between-group comparison was performed using a paired t-test for quantitative variables. Statistical significance was measured using an alpha level of 0.05.

**Ethical Considerations**

Institutional Review Board (IRB) approval was obtained prior to beginning data collection (see appendix D for IRB application). Expedited IRB approval was requested to complete the review of charts. The owners of the practice were contacted and gave permission to perform the analysis at the fertility center. All subjects were kept anonymous with coding for each patient. Spreadsheet coding data was kept on a password protected computer and all identifying information was removed upon entry into the file.

**Internal and External Validity**

To confirm the absence of confounding factors only cycles where no additional supplementation therapy were included, this excluded cycles where additional adjuvant treatment was given, including dexamethasone and letrozole. Patients with a BMI under 18 or over 35 were also excluded, as this can affect cycle outcomes. Patients included in the study had to complete the cycle without growth hormone first then the cycle with the adjunct therapy of growth hormone. Patients who completed more than 2 cycles using growth hormone, only the first cycle was included in the study to prevent bias in choosing cycles with better outcomes. A study performed by Dakhly et al., (2018) guided the design of the study to include different COH protocol types to ensure external validity of the study. The study will also include a number of demographic variables using purposive sampling to ensure a diverse sample of patients so that results are generalizable to different populations.
Bias

To prevent bias, patients undergoing multiple COH cycles with growth hormone, only the first oocyte retrieval will be considered. Due to the study design patients are not randomized, there is a potential for selection bias. Purposive sampling and over sampling may modify this bias.

Summary

Data was collected from 12 fertility patients. The participants had to have undergone two COH cycles, one with growth hormone supplementation and one without. The data collected was analyzed using paired t-tests to see if there is a correlation between receiving growth hormone treatment and the number of mature oocytes retrieved. SPSS was used to complete the analysis and reach conclusions for this study. Biases were taken into consideration such as multiple cycles.
CHAPTER 4: GRANT ELEMENTS

The concluding chapter of this proposal will explore the principal components of the grant proposition. This chapter will discuss three institutions that would be appropriate to apply for this grant. This will include the description of the completed grant selection, as well as an analysis of the budget, including budget justification. The final dissemination plan will be reviewed, as well as a timeline of events.

For Proposal: Three Potential Grants

The Sigma Theta Tau Organization mission is to improve healthcare everywhere by developing nurse leaders and connecting and empowering them (sigmanursing.org, 2021). Sigma Theta Tau was founded in 1922, became an incorporated nonprofit organization in 1985 and has more than 135,000 active members (sigmanursing.org, 2021). The Sigma Small Grants Research Funding bases allocation of funds on the quality of the proposed research, the research budget as well as the promise of the applicant (sigmanursing.org, 2021). The Small Grant Research funding encourages new researchers who have no other funding to apply with preference going to Sigma members (sigmanursing.org, 2021). Sigma Theta Tau offers a number of different grants in many areas of nursing. Sigma Theta Tau supports any novice researcher that meets the criteria and is applicable for my grant research.

Research on growth hormone in infertile patients is relevant to nursing by staying knowledgeable in current healthcare treatment in order to support fertility patients both physically and mentally. Sigma Theta Tao gives out between 10-15 grants annually with a maximum amount of $5000 (sigmanursing.org, 2021). The deadline to apply for the grant application deadline is December 1, 2021 and funding will be awarded June 1, 2022.
The National League of Nursing (NLN) is the leading organization of leaders in nursing education and nurse faculty (nln.org, 2021). The NLN was the first nursing organization in the United States, founded in 1893 as the American Society of Superintendents of Training Schools for Nurses (nln.org, 2021). The nln.org (2021) has a long history of supporting studies of the highest quality that contribute to the academic process. The NLN offers professional development, teaching resources, research grants, testing services and public policy initiatives to its 40,000 individual members and 12,000 institutional members, encompassing nursing education programs across higher education and healthcare (nln.org, 2021). The NLN would support my grant proposal on research to investigate the outcome of the use of growth hormone in fertility patients. Little education is given during Family Nurse Practitioner Programs regarding women’s health, though it is a growing specialty. There is a need for more nursing led research on fertility treatments.

The NLN Research in Nursing Education Grants Program supports studies of exceptional research that contributes to the development of nursing education (nln.org, 2021). The NLN awards roughly 5 research proposals annually with up to a maximum of $30,000 to individual members and faculty of schools who are members of NLN (nln.org, 2021). The NLN will allocate funds by the 1st of September for the year awarded (nln.org, 2021). To obtain a grant from the NLN, the proposal must meet one of the NLN priorities, build the science of nursing education, build faculty teaching practices, create partnerships and build a workforce that can meet the needs of nursing education, staff, and healthcare (nln.org, 2021). Building nursing education through innovative teaching by staying current on new and novel fertility treatments, as well as promoting the Nurse Practitioner (NP) role in fertility treatment.
Final Grant Selection

The National Institutes of Health (NIH), is the United States medical research agency. It’s mission it to obtain knowledge about living beings and to apply that knowledge to promote health, enhance lifespan, while reducing illness and disabilities (National Institutes of health [NIH], n.d.). The NIH acknowledges that once diagnosed with infertility, the rate of successful treatment is 50% and has created a couple of Funding Opportunity Announcements for fertility research (NIH, n.d.). Among these opportunities is Research Project Grant (RO3) number PA-18-488, this is the NIH Small Grant Program.

The Small Grant Program will provide limited funding for a short period of time to support a variety of projects, which includes, collection of preliminary data, pilot or feasibility studies, secondary analysis of existing dates and small, self-contained research projects, and new research development (NIH, n.d.). It is limited to two years of funding and generally costs given up to $50,000 per year and is not renewable (NIH, n.d.). The NIH Small Grant Program will work well within for the proposed study with ample funding and timeline.

Budget

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### Equipment (Itemize)

- Laptop computer: $799.99
- Wireless printer: $300.00
- Back-up external hard drive: $300.00
- Bit locker encrypted software: $100.00

Total Equipment: $1,499.99

### Supplies (Itemize by category)

- SPSS IBM 2.0: $1,300.00/Annual Subscription.
- General office supplies: $40.00/1000 sheets

Total Supplies: $1,340.00

### Dissemination

- ASRM Congress Expo for Non-member Clinicians/Students: $450.00
- Costs for poster, printing and materials: $300.00
- Currently Scheduled to be Virtual, Travel cost: $0.00

Total Dissemination: $469.00

### Subtotal Direct Costs for Initial Budget Period

$17,128.00

---

**Budget Justification**

**Danielle Miller:** MSNc, RN is the primary investigator of this study in determining the effect of Growth Hormone on a controlled ovarian hyperstimulation cycle. Danielle has been employed as a clinical nurse coordinator for eight years of her career in nursing. At present, Danielle is enrolled in the Family Nurse Practitioner program at California State University San Marcos where she has researched and developed the proposed study. Danielle will be guided by her research chair, Susan Andera throughout the completion of the study. A statistician will also be hired to ensure accuracy throughout the 2-month period. Danielle will be the primary data collector and will complete the data analysis. It is estimated that Danielle
will spend approximately 80 hours on site and is asking $65.00 per hour which would come to a total of $5,200.00 that she is requesting over the entire study period.

**Dr. Susan Andera PhD, MN, NP-C:** Dr. Andera will be the mentor and advisor on the research methods to ensure successful completion of the study. Dr. Andera will allocate roughly 60 hours over the course of the study and will be paid $60.00 per hour which equals a total cost of $3,000.00 for the entire grant proposal.

**Dr. L. Michael Kettel:** Dr. Kettel will be the co-chair, mentor and medical expert on the medical piece of the study to ensure authenticity. Dr. Kettel will allot approximately 60 hours over the course of the study and will be paid $60.00 per hour which is a total cost of $3,000 for the entire grant proposal.

**Consultant:** The research team will hire a statistician that will be responsible for the coding of demographic data, inputting data into the SPSS 21.0 analysis software, and facilitate analysis and interpretation of the findings. This candidate will preferably be a master prepared statistician with experience in statistical analysis of data in research studies. The average statistician earns $125/hour and is estimated to work 18.5 hours total during the study. To hire a statistician for the research study the end cost would be $2,320.

**Equipment:** Laptop computer, encrypted software, external hard drive: A laptop computer is necessary for the research study to input, store and analyze data. A external hard drive back up, as well as encrypted software are also required for the study. The estimated total cost for this equipment, including 7.25% California tax is 1609.24 (379.99/computer + 300/external hard drive + 100/encrypted software + tax = $1609.24).

**Supplies:** The SPSS IBM 21.0 software is required to run data analysis and can be purchased for $1300.00 for a year. A one-year subscription is adequate for the duration of the research
study. General office supplies: General office supplies including copy paper ($40/1000 sheets), and copier expenses (0.75/400 pages) are all essential for the research study for generating flyers, filling out consent forms, sleep logs and completing questionnaires. The estimated expense for these items is $1640.00.

**Travel:** The PI lives works at the clinic in which the study is taking place therefore review will be performed both before and after work hours. The PI is allotting 5 trips to and from the clinic. The approximate cost of gasoline is based on 5 round trips to and from the research site including the collection phase. The cost of gasoline is based on $3.4/gallon or 15 cents per mile. The total estimated expense is $31.00 including sales tax.

The findings from the proposed study would be disseminated at the American Society of Reproductive Medicine Annual meeting in 2022. Prices were based on the location of the 2021 conference which will be held virtually. The cost to attend for clinicians/students is $469.00. Cost for poster presentation is $300.00.

**Timeline**

The study timeline will be over a 6-month period including data collection and dissemination. The data collection process will take place over a three-month period from December 1, 2021 to February 1, 2022, this is to ensure ample time for data collection for a large enough sample size. Data collection will be done by the PI and inputted into excel spreadsheets.

Finally, the month of March will be devoted to data organization and analysis with the utilization of SPSS software and a statistician. The outcomes of the study will be exhibited in a thorough and precise manner using charts and graphs used throughout the study. Once data
analysis is completed, the study will be sent to the selected journals for publication. Beginning April 1, 2022 through May 2022 the time will be used to disseminate the findings. The conclusions found during the study will be sent to ASRM to apply for a poster presentation at the annual conference for 2022. The study will be completed in 6-month timeline and stay within the proposed grant budget of 20,000 dollars.

**Timeline of Events**

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Event Description</th>
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</thead>
<tbody>
<tr>
<td>November 1, 2021 – February 1, 2022</td>
<td>Recruitment of participants via chart review.</td>
</tr>
<tr>
<td>February 1, 2022</td>
<td>Deadline to collect sample size.</td>
</tr>
<tr>
<td>February 2, 2022 – March 1, 2022</td>
<td>Review of embryology reports</td>
</tr>
<tr>
<td>March 2, 2022 – April 1, 2022</td>
<td>Statistical analysis and dissemination of findings.</td>
</tr>
</tbody>
</table>

**Plan for Dissemination**

**Journals.** The findings collected through this grant proposal will be submitted to three chosen journals which will include, Fertility and Sterility, The Journal of Reproductive Endocrinology and Infertility and The Journal of Nurse Practitioners. Fertility and Sterility is an open access journal that publishes original scientific articles in clinical and laboratory research relevant to reproductive endocrinology, urology, andrology, physiology, immunology, genetics, contraception and menopause (Fertility and Sterility, n.d.). The journal is the official journal of the American Society of Reproductive Medicine (Fertility and Sterility, n.d.) Fertility and Sterility encourages meaningful clinical research and promotes excellence in professional education for the specialty of reproductive medicine.
The Journal of Reproductive Endocrinology and Infertility is a peer reviewed open access journal including topics such as polycystic ovarian syndrome, endometriosis, hypothalamic pituitary dysfunction, menstrual disorders, menopause & hormone replacement therapy, congenital adrenal hyperplasia, tubal factor infertility, preimplantation genetic diagnosis, male factor infertility, in-vitro fertilization, fertility preservation, congenital uterine anomalies, other disorders of the female reproductive tract and care of pregnant women (The Journal of Reproductive Endo…., n.d.). The Journal of Reproductive Endocrinology and Infertility encourages their authors to share their research outcomes using their platform and give the readers updated and important information (The Journal of Reproductive Endo…., n.d.).

Finally, The Journal of Nurse Practitioners is a high-quality, peer reviewed journal with original research, continuing education and a variety of departments that help the reader excel as providers ranging from acute care to primary care (The Journal of Nurse Practitioners, n.d.). Each issue meets practice needs while encouraging both discussion and feedback with articles that are thoughtful and often times controversial (The Journal of Nurse Practitioners, n.d.). The journal is published 10 times per year and is associated with both The American Association of Nurse Practitioners and the Australian College of Nurse Practitioners.

Conferences. The findings obtained through this grant proposal would be presented at the American Society of Reproductive Medicine Scientific Congress and Expo (ASRM) annual meeting in October of 2021. The annual meeting in 2021 will be held in Baltimore, Maryland from October 16-20, 2021, currently is still planned to be held virtually. The October 2022 conference will be held in Anaheim, California. ASRM is a multidisciplinary organization dedicated to the advancement of the science and practice of reproductive medicine (ASRM,
n.d.). This is accomplished through excellence in education and research and through advocacy for patients, as well as physicians and affiliated providers (ASRM, n.d.).

This meeting includes a number of presentations, post-graduate courses, debates, poster presentations and abstracts on topic of infertility treatment (ASRM, n.d). The research outcomes of the proposed grant would be presented as a poster presentation at this conference. The attendance fee for this conference is $469.00 for Non-Member Clinicians/Students. The ASRM annual conference would serve as a fitting forum to present results on human growth hormone’s effect on the number of mature oocytes yielded during a controlled ovarian hyper stimulation cycle.
Reference


Figure 1. Hormone Roles in Female Reproduction. The “GH” refers to growth hormone and IGF-1 refers to insulin-like growth factor. The dotted lines and normal text refer to emergency modulation of ovarian function, while the solid lines and italic text refers to strategic maintenance of ovarian function (Hull & Harvey, 2001).
Figure 2. Love and belongingness needs include friendship, intimacy and family, while esteem needs can be classified as the need the achieve dignity, achievement and fulfillment (Mcleod, 2020). Full Description: Pyramid of needs. Base category “Basic needs” has two layers, the bottom is purple with text “Physiological needs: food, water, warmth, rest” the other layer is green with text “Safety needs: security, safety.” Middle category “Psychological needs” has two layers, the yellow level has the text “Belongingness and love needs: intimate relationships, friends” the blue level has the text “Esteem needs: prestige and feeling of accomplishment”. The top category “Self-fulfillment needs” is orange and has the text “Self-actualization: achieving one’s full potential, including creative activities”.
Appendix C

Figure 3. G-Power Plot (Faul, 2014)
### Appendix D

**California State University SAN MARCOS**

**Limited/Expedited or Full Review Application Form**

**Instructions:**
Please fill out this application form using clear language and lay terms. Please answer each section as completely and as concisely as possible. Some questions may not apply to your study. In that case, please add “not applicable” in the text box. Please upload this application form along with additional documents that are supplemental (as applicable) to your submission in IRBNet. For more information, please visit the IRB website. For questions, please contact IRB office at (760) 750-4029 or irb@csusm.edu.

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<td>Proposed Start Date</td>
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**Faculty/Staff Investigator:**

<table>
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<th>Name</th>
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</tr>
</thead>
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<tr>
<td></td>
<td></td>
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Phone Number:  
Email:  
Date CITI Training Completed:  

**Student Investigator: (if the student is the principal investigator)**

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Danielle Miller</td>
<td>School of Nursing/CSUSM</td>
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Phone Number: (XXX) XXX-XXXX  
Email: XXXXXXXXX@csusm.edu  
Date CITI Training Completed: 3/5/2019

<table>
<thead>
<tr>
<th>Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Susan Andera</td>
<td>School of Nursing</td>
</tr>
</tbody>
</table>

Phone Number: (XXX) XXX-XXXX  
Email: XXXXXXXX@csusm.edu  
Date CITI Training Completed:  

**REMINDER:** Once the student investigator has completed this application form, he or she must e-mail it to their faculty advisor for review and feedback. Once the faculty advisor gives permission to the student to move forward, then the student will upload this application form along with additional documents to IRBNet. Once the student uploads all the documents, then s/he will share the IRBNet package with the faculty advisor. The faculty advisor must have an IRBNet account to approve the package as the “advisor” by logging into IRBNet. The faculty advisor will receive a notification via e-mail that the package has been shared with them and that they need to sign the package in IRBNet. Please do not “submit” your package in IRBNet until your faculty advisor has signed your package. For more information, please visit the IRB website.

**Checklist:** Check the additional documents that are uploaded in IRBNet. Check ALL that apply:

- [x] CITI Training Certificate for the principal investigator and the faculty advisor, if applicable.
- [x] Letter of support (if you are collecting data off campus, you need to provide a letter of support from the research site. The letter of support must include the letterhead of the organization and list the research activities to provide evidence that the organization is knowledgeable about the study.

- [ ] Survey(s), questionnaire(s), and/or interview questions. If you are using an online survey, please upload a PDF copy of the survey.

Revised 01/14/2019  Page 1
### Checklist (continued...)

- [ ] Recruitment flyer(s), script(s), or advertisement for newspaper, listserv, radio, or TV.
- [ ] Consent and child assent form(s) or information sheets. You must provide a separate form for each population group. Please use consent and assent form templates on IRB website. The information provided in this application form must match with the information provided in the consent form or information sheet.
- [ ] Ed.D. students in the Joint Doctoral Program Only: Sign, scan, and upload the UCSD-CSUSM JDP IRB Cover Sheet in IRBNet.
- [ ] Verification of translation form (Only for consent and/or assent forms in languages other than English and Spanish)

### 1. Type of Review (Please select one.)

- [ ] Limited/Expedited Review: Research studies that are minimal risk qualify for limited/expedited review. These studies include, but are not limited to: benign interventions that involve children (e.g. lab studies) and secondary research that involves collection of identifiable biospecimens where broad consent is required. If limited/expedited review is selected, your submission will be assigned and reviewed by an IRB committee member within three weeks.

- [ ] Full Review: Research studies that are more than minimal risk are qualified for full review. If full review is selected, your submission will be reviewed by the IRB committee at a bi-monthly scheduled meeting during the academic year. The IRB committee does not meet during summer.

### 2. Funding: Is this research study funded?

- [ ] Yes  [ ] No

If yes, please check one below:

- [ ] Internally funded
- [ ] Externally funded: → Please provide the funding source:

### 3. Purpose of Project

Describe the goal(s) of your project. List your research question(s) and discuss why the question is important, and how your study will attempt to answer it. Include how your literature review supports this with at least three citations. [Please do not exceed two paragraphs. Please use lay language.]

See attached.
### 4. Number of Participants

A) Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval. If you have more than one population group, please list the expected number of participants for each population group in your research study.

The desired sample is 12 participants.

B) Is this a multi-site study?

- [ ] Yes -- if yes, indicate the total number of participants to be enrolled across all sites
- [x] No

### 5. Participant Population

A) Describe all characteristics of participants including their primary language, age, gender, ethnicity, and vulnerabilities. Explain why you are targeting this specific population.

The participants will be patients at a local fertility center undergoing a controlled ovarian hyperstimulation cycle using the adjunct therapy of growth hormone. Participants will be females under the age of 40 undergoing 2 controlled ovarian hyperstimulation cycle, one with the use of growth hormone and one cycle without.

B) Indicate whether anyone might be excluded from participating in your research study. If so, please explain why.

The exclusion criteria for this study is BMI over 35, patients over the age of 45, patients who only completed one cycle, cycle cancellation, mini-stimulation cycle types and those that used additional adjunct therapies beyond growth hormone.

### 6. Participant Recruitment

A) How will you find, recruit, or identify potential subjects? How will you select the final group of participants from those who expressed interest in participating in your study? REMINDER: Please upload flyers, posters, or other oral or written invitations or recruitment script used to recruit potential participants in IRBnet.

Potential subjects will be identified by chart review for patients who have undergone two controlled ovarian hyperstimulation cycles, one without growth hormone use and one with growth hormone.

B) Will participants receive compensation or other incentives?

- [x] Yes
- [ ] No

If yes, please explain the type (e.g. course credit, gift cards, cash payment, parking, etc.), the amount and timing of compensation or incentive. Compensation plans should be incremental (not contingent upon study completion) to avoid coercion or undue influence.
### 7. Informed Consent Process

**REMINDER:** Please upload the consent (and child assent, if applicable) form, information sheet if requesting a waiver of consent or a waiver of documentation of consent, or broad consent form in IRB Net.

A) If participants are 18 years old or older, how and when will you explain the study including the required elements of informed consent to participants? How and when will participants receive the adult consent form?

Not applicable

B) If your study includes participants younger than 18 years old, how and when will you explain the study including the required elements of informed consent to parents and children? How and when will the parent receive the parent consent form? How and when will the child receive a verbal explanation of the study (if age 7 and younger) or the child assent form (for ages 8-17)? [Please note that signed parent consent form must be received before obtaining child assent to participate in the study.]

Not applicable.

C) Will you or a student/research assistant obtain consent from participants?

This is a retrospective study that will use de-identified lab data, no consent required.

D) How much time will participants have to consider participating between the explanation of the study, the receipt of the consent form (and child assent form, if applicable), and the beginning of the study? [Please note that participants should be given sufficient time between when participants receive the consent/assent form and when they are expected to sign and return the form to avoid coercion or undue influence.]

Not applicable

E) Are you requesting a Waiver of Consent or a Waiver of Documentation of Consent for collecting data other than secondary research for which consent is required? [Please note that electronic signatures are accepted as documentation of consent, so you do not need to request a Waiver of Documentation of Consent if you plan to obtain electronic signatures. Additionally, you cannot request a waiver of consent if the research involves more than minimal risk.]

- [ ] Yes  
- [ ] No

If yes, please explain:

1. how the research cannot practically be done without the waiver of consent or a waiver of documentation of consent, AND
2. how participants will be provided information about the study including the required elements of informed consent with an information sheet or verbally?

Not applicable.
F) If your study will use incomplete disclosure of the purpose of the study or deception, explain the incomplete disclosure or deception, and provide a rationale explaining why it is necessary for the research.

Not applicable.

G) If you will ask participants for broad consent for the use of identifiable private information or identifiable biospecimens, list the specific future uses of the information or biospecimens for which participants are giving consent.

Not applicable.

H) If using secondary research where broad consent has already been obtained for collecting, storing, and maintaining identifiable private information or identifiable biospecimens, explain the informed consent process that was followed to obtain consent from participants.

Not applicable.

I) If any participants are not fluent or comfortable with English, please explain how you will ensure that participants understand the research activities and required elements of informed consent before giving their consent to participate in your study.

REMEMBER: If participants need consent and/or assent forms in a language other than English or Spanish, the researcher must upload Verification of Translation form in IRBNet after the English version of the consent form has been reviewed and approved.

Not applicable.

8. Data Collection and Procedures
A) Describe the type of data you plan to collect as part of your research study. Please check ALL that apply.

- [ ] Biospecimens (including blood, urine, saliva, hair, sweat, etc.)
- [ ] Surveys, questionnaires, or interviews
- [ ] Observation of participants
- [x] Audio, video, image, digital or non-digital records
- [ ] Other: ________________________________
B) Please provide a step-by-step explanation of how you will collect the type of data you checked above in the order it occurs. Additionally, indicate the duration of each data collection method as applicable. For example, if using surveys, questionnaires, or interviews, explain how often participants will be asked to complete them and how long it will take for participants to complete them. If using biospecimens, explain how much and how many times biospecimens will be obtained from the participants.

REMININDER: Please upload a copy of the survey(s), questionnaire(s), interview(s) and/or observation protocol (if applicable) in IRBNet.

Chart review. Look through charts by hand to find patients who have undergone to controlled ovarian hyperstimulation cycles, one without the adjunct treatment of growth hormone and one using the growth hormone. Once the appropriate sample size is achieved, lab data will be reviewed looking at the number of mature oocytes produced for each cycle and comparing the two cycle outcomes.

C) Provide the projected dates/timeframe in which you plan to conduct your research study starting with the informed consent process. Include when each data collection will take place.

The projected timeframe for the research study will take place during the November of 2021 to February 2022.

9. Risks and Inconveniences

A) Explain potential risks and/or inconveniences for each population group and data collection method mentioned above in section 8A. Risks may be physical or psychological (e.g., strong emotional reactions to researcher’s questions). Inconveniences may include time required to participate in the research study. [Please be sure the risks listed here match the risks listed in your consent form or information sheet.]

Not applicable

B) If applicable, please select which of the following vulnerable population will be involved in your research study:

☐ Prisoners
☐ Children
☐ Other vulnerable populations such as persons with impaired decision-making capacities, economically or educationally disadvantaged persons, etc.

C) Describe any special risks to vulnerable populations.

Not applicable.
10. Safeguards

Please identify a safeguard for each risk you mentioned in section 9A. Explain how you will minimize each risk. If there is a risk for participants to have a strong emotional response or a physical inquiry, please list referrals and/or resources that may be offered (e.g., clinics or shelters, medical or psychological referrals). [Please be sure the safeguards listed here match the risks listed in your consent form or information sheet.]

Not Applicable

11. Data Management and Confidentiality

A) Please explain how the consent and assent forms will be secured. Add the duration of time these forms will be kept and how they will be disposed. [These forms should be stored separate from the rest of the data collected as part of the study. They must be kept in a secure place for three years by the researcher.]

No applicable

B) Will personal identifying data (e.g. participants' names, phone number, home and/or e-mail address, student ID, birth date, etc.) be recorded?

- Yes  - No

If yes, explain what information will be recorded, how this information will be stored, and how you will protect the identity of the participants.

Not applicable

C) Please explain who will have access to the data collected, where and how data will be stored (e.g. password protected computers, locked filing cabinets, cloud storage, etc.), how long the data will be stored and how it will be disposed.

The primary researcher, faculty Chair and Co-Chair will have access to the collected data. All data will be de-identified, kept private and secure in a password-protected computer hard drive with a digital back-up on an encrypted password-protected account. Only the researcher, faculty chair and co-chair will have access to the data. All data will be deleted three years after the completion of the study.

D) If biospecimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

Not applicable.
10. Location of Study

Where will the research be conducted? Describe any risks to the participants or confidentiality issues related to using this location. [If your research study involves multiple sites, describe risks and confidentiality issues for each research site.]

REMININDER: If you are collecting data off campus, please upload the Letter of Support from the organization in IRBNet.

The research will be conducted at a local fertility center. Only one location will be used for the study. The risks of using this location is the presence of patients and participants that are not in the study. Risks can be decreased by collecting data after business hours or on weekends. All charts used for the study will be placed in a locked office with a locked filing cabinet.

13. Safety Monitoring (Only for studies that are more than minimal risk and need full review)

Please explain how you will periodically evaluate the data collected regarding harms and benefits to determine whether participants remain safe.

Not applicable

14. Data Sharing (Only for studies that include multiple research sites)

Please explain how you will store and share data across multiple research sites and who will have access to it.

Not applicable, one research site.

15. Alternative to Study Participation (If Applicable)

Describe alternative activities non-participants could do during data collection. For example, if conducting a survey in the classroom, explain how those who decided not to participate in the study will spend their time while participants take your survey.

Not applicable.
16. Participant Debriefing or Feedback (If Applicable)

Describe any feedback or information you will offer participants at the end of the study. [If deception is involved in your research, participants must be debriefed about the nature of the study as soon as possible. Participants must be made aware of the incomplete disclosure of the purpose of the study or deception, including their right to withdraw any record of their participation. You may consider giving the opportunity for participants to request a copy of the results of the study.]

Not applicable

17. Study Benefits

A) Discuss any potential individual and/or societal benefits. [Please note that often there is no direct benefit for the participants, however, the study contributes to the literature or future research.]

The study benefits future care for patients undergoing fertility treatment by looking at the outcome of controlled ovarian hyperstimulation cycles with the addition of growth hormone.

B) Please explain how the benefits from this study exceed the risks to participants?

There is no risk in participating in this study as all the data is being collected retrospectively.

18. Qualifications of the Researcher(s)

A) Briefly outline the principal investigator's qualifications and experiences related to the research study.

The principal investigator is a Registered Nurse with fifteen years of clinical nursing experience in the Emergency department caring for patients with a number of medical problems. The primary investigator has worked for the past 7 years at a fertility center with the last year as the Clinical Lead. The principal investigator has assisted in the data collection for a number of articles written for the American Society of Reproductive Medicine abstracts.

B) If the principal investigator is a student, include faculty advisor's qualifications.

Dr. Susan Andera, PHD, MN, NP-C. Family Nurse Practitioner Track Coordinator
C) If using student or research assistants, please explain how you will ensure that these assistants are trained and qualified to assist the project including obtaining consent forms and collecting data. All assistants must complete the CITI training before starting to work on the project. It is the faculty member's responsibility to keep a copy of student assistants' CITI training certificate on their record.

Not applicable.

19. For Student Principal Investigators Only
Please check the box below to verify that you will share your package and obtain your faculty advisor's signature in IRBNet:

☑️ I verify that I will share my package with my faculty advisor in IRBNet after I upload this application and other materials, but before submitting the package for review.
Appendix E
COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- Name: Danielle Miller (ID: 7964881)
- Institution Affiliation: California State University San Marcos (ID: 1073)
- Institution Email: mille413@cougars.csusm.edu
- Phone: 6616093104

- Curriculum Group: Social & Behavioral Research (except for School of Education) - Basic/Refresher
- Course Learner Group: Same as Curriculum Group
- Stage: Stage 1 - Basic Course
- Description: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- Record ID: 30816931
- Completion Date: 05-Mar-2019
- Expiration Date: 04-Mar-2022
- Minimum Passing: 80
- Reported Score*: 95

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For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?kfed85cc6-909c-472b-a2ac-5a5b2cb4a4f0-30816931](http://www.citiprogram.org/verify/?kfed85cc6-909c-472b-a2ac-5a5b2cb4a4f0-30816931)

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: [https://www.citiprogram.org](https://www.citiprogram.org)
**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)**

**COMPLETION REPORT - PART 2 OF 2**

**COURSEWORK TRANSCRIPT**

**NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.**

- **Name:** Danielle Miller (ID: 7964881)
- **Institution Affiliation:** California State University San Marcos (ID: 1073)
- **Institution Email:** mille413@cougars.csusm.edu
- **Phone:** 6616093104

- **Curriculum Group:** Social & Behavioral Research (except for School of Education) - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Record ID:** 30816931
- **Report Date:** 18-Mar-2021
- **Current Score:** 95

### REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES

<table>
<thead>
<tr>
<th>Module</th>
<th>MOST RECENT</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Students in Research (ID: 1321)</td>
<td>05-Mar-2019</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>Defining Research with Human Subjects - SBE (ID: 491)</td>
<td>05-Mar-2019</td>
<td>5/5 (100%)</td>
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<tr>
<td>The Federal Regulations - SBE (ID: 502)</td>
<td>05-Mar-2019</td>
<td>5/5 (100%)</td>
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<tr>
<td>Belmont Report and Its Principles (ID: 1127)</td>
<td>05-Mar-2019</td>
<td>3/3 (100%)</td>
</tr>
<tr>
<td>Records-Based Research (ID: 5)</td>
<td>05-Mar-2019</td>
<td>3/3 (100%)</td>
</tr>
<tr>
<td>Assessing Risk - SBE (ID: 503)</td>
<td>05-Mar-2019</td>
<td>4/4 (80%)</td>
</tr>
<tr>
<td>Informed Consent - SBE (ID: 504)</td>
<td>05-Mar-2019</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>Privacy and Confidentiality - SBE (ID: 505)</td>
<td>05-Mar-2019</td>
<td>5/5 (100%)</td>
</tr>
<tr>
<td>History and Ethical Principles - SBE (ID: 490)</td>
<td>05-Mar-2019</td>
<td>4/4 (80%)</td>
</tr>
</tbody>
</table>

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?kfed85cc6-909c-472b-a2ac-5a5b2cb4a4f0-30816931](http://www.citiprogram.org/verify/?kfed85cc6-909c-472b-a2ac-5a5b2cb4a4f0-30816931)

Collaborative Institutional Training Initiative (CITI Program)

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