

***Nutrition Through the Life Cycle 6th edition Brown
Solutions Manual***

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Instructor's Manual¹ for Chapter 2 – Preconception Nutrition

Resources Included in This Document

1. Lists of chapter learning objectives and key terms
2. “Lecture launcher”: caffeine and fertility
3. Assignment worksheets with answer keys: preconception nutrition, personal iron and vitamin C intakes
4. Answer keys for textbook case studies 2.1 and 2.2
5. Chapter outline/summary
6. List of relevant websites organized by topic
7. Internet activities: (A) folic acid intake, (B) Baby Center site evaluation, (C) NLM research
8. Discussion questions
9. Classroom activities: (A) nutritional assessment tool development, (B) nutrition for contraceptive users, (C) “healthy sperm diet,” (D) black cohosh research

Learning Objectives

- 2.1 Cite three examples of the Healthy People 2020 nutrition-related objectives for the preconception period.
- 2.2 Identify six major hormones involved in the regulation of male and female fertility processes, and identify their source and effects on the regulation of fertility processes.
- 2.3 Describe the potential effects of nutrition-related factors such as body fat content, iron status, and alcohol intake on fertility in females and males.
- 2.4 Cite four examples of relationships between nutrient intake and nutritional status during the periconceptional period and the outcome of pregnancy.
- 2.5 Develop a one-day menu for a preconceptional woman and a man based on the ChooseMyPlate.gov food guidance materials.
- 2.6 Identify three nutrition-related consequences that may be related to the use of combination hormonal contraceptives, and a consequence that is related to the use of estrogen or progestin contraceptives only.
- 2.7 Cite three important nutrition-related components of preconceptional health care.
- 2.8 Describe the four steps of the Nutrition Care Process.

Key Terms

infertility	menstrual cycle	body mass index (BMI)
infecundity	hypothalamus	anovulatory cycles
fertility	pituitary gland	amenorrhea
fecundity	corpus luteum	antioxidants
miscarriage	prostaglandins	free radicals
fetus	testes	gene variant
endocrine	androgens	periconceptional period embryo
immunological	epididymis	DNA methylation
subfertility	semen	neural tube defects (NTDs)
puberty	pelvic inflammatory disease (PID)	small for gestational age
ova	endometriosis	dietary folate equivalents (DFE)
menopause	leptin	allele

¹ revised by Nadine Kirkpatrick, Sacramento City College, and Carrie King, University of Alaska at Anchorage; originally by U. Beate Krinke, University of Minnesota

Lecture Launchers

- **Caffeine as contraceptive?** High intakes of caffeine “may delay conception” (see page 59). Help students understand what “high levels of caffeine” means by bringing two visuals: a 16-oz coffee shop take-out cup would provide the roughly 300 mg of caffeine that decreased chances of conception by 27% per cycle in one of the studies cited; 32 oz (a quart) provides over 500 mg caffeine, which cut conception rates in half over a 10-month period in another study. [Table 2.4, Caffeine content of foods and beverages.]
- **Highlight factors related to altered fertility** in men and women listed in Table 2.3, page 56. [Delays in contraception attributed to caffeine also provide an excellent opportunity to explore the levels and quality of researched links between nutrition and conception. When is the evidence enough to make public recommendations? Do we use different standards when making recommendations during pregnancy?]

Worksheet Answer Key (worksheets appear at the end of this document)

Worksheet 2-1: Preconception Nutrition Counseling

1. Oral contraceptives might cause increased blood levels of triglycerides and LDL cholesterol (p. 64 - 65). Considering her family history of heart disease and type 2 diabetes, and the absence of current lab work, it would be prudent to recommend she see her health care provider to have current lipids and glucose labs drawn. Based on the results of these labs, she may want to discuss alternative forms of contraception with her provider, including changing the type of oral contraceptive.
2. BMI = 28.2 isn't associated with compromised fertility; history of iron-deficiency anemia could interfere with fertility, so she should have current iron levels checked; caffeine intake is excessive and may interfere with fertility.
3. Continue and/or increase current level of physical activity, decrease caffeine intake, have annual physicals including lab work, and follow an individualized meal plan according to the USDA Food Patterns (available via the ChooseMyPlate.gov website).

Worksheet 2-2: Iron and Vitamin C Intake – Answers will be individualized.

Textbook Case Study Answer Key²

Case Study 2.1: Cyclic Infertility with Weight Loss and Gain

1. Underweight.
2. No. (BMI correlates with body fat content in groups of people, but does not indicate an individual's level of body fat.)
3. There could be several different reasons why Tonya stopped ovulating. One reason could be her loss of body fat and alterations in reproductive hormone levels that are sensitive to body fat content. This is supported by the return of menstruation and ovulation after Tonya gained weight. This case is not the only clinical picture observed in women experiencing amenorrhea after weight loss. In some cases, FSH is low and LH release and levels are normal; other cases are characterized by elevated estrogen levels; and so on. Each case must be considered individually.
4. Her average estrogen level likely decreased.

² Contributed by Judith E. Brown.

5. Fertility-enhancing drugs may not induce ovulation in underweight women; becoming pregnant while underweight increases the likelihood of adverse pregnancy outcomes; and the initial treatment approach recommended for weight-related amenorrhea is weight gain.

Case Study 2.2: Male Infertility

1. Mr. Trigger's BMI is 37.2 kg/m².
2. Obesity due to excessive energy intake and inadequate physical activity.

Note: The nutrition care process emphasizes prioritizing and focusing on one diagnosis. Part of the diagnosing step is to consider the etiology/cause behind the nutrition diagnosis/problem.

3. Students should identify evidence-based methods for achieving sustainable weight loss, increases in physical activity level, or both. The intervention would focus on the obesity problem. It would aim to reduce the client's extra calorie intake and to implement effective methods for increasing physical activity.
4. Examples of nutrition-related indicators that could be used to monitor and evaluate the interventions:
 - Weight, BMI, weight loss
 - Physical activity level
 - Achievement of behavioral change goals or other changes related to the selected interventions
 - Normal sperm count
 - Quality of life indicators
 - Client adherence to nutrition care plan

Chapter Outline

I. Introduction

Chapter 2 develops a vocabulary that will be new for many students. Students with biology, anatomy, and physiology expertise will have an edge over those who are not familiar with reproductive processes.

II. Preconception Overview

This section distinguishes between the definitions of fertility (actual production of children, typically as rate or number of children born per 1000 women aged 15-44) and fecundity (the biological capacity to bear children). The common meaning of infertility (biological inability to bear children) is used throughout. Regular, unprotected intercourse leads to a 25-30% chance of pregnancy within one menstrual cycle in healthy couples; however, 30-50% of conceptions do not continue to develop to the fetal stage due to resorption into the uterine wall or miscarriage in the first 20 weeks of pregnancy. An important concept emphasized by Table 2.1 (p. 52), listing Healthy People 2020 nutrition objectives, is that goals for preconceptional health apply to men and to women.

III. Reproductive Physiology

Section highlights are presented in Illustrations 2.1 and 2.2 (pp. 53, 54). Females are born with a full set of ova that are used up by menopause, whereas males are born with sperm-producing capabilities that last throughout the life span. The rise and fall of estrogen and progesterone levels affect menstrual cycles in women; in males, reproduction is an ongoing rather than a cyclic process. Testosterone stimulates the maturation of sperm, which takes 70-80 days. Table 2.2 (p. 55) provides an overview of hormones that affect reproduction.

Endocrine abnormalities and "unknown causes" are the leading infertility diagnoses. Sources of disruption are summarized in Table 2.3 (p. 56).

IV. Nutrition and Fertility

Undernutrition can be chronic or long term and is associated with delivery of small, frail infants with a high likelihood of death in the first year. There is a 10-fold infant death rate difference between poor and developed countries, although studying chronic undernutrition is complicated by factors such as varying contraceptive practices, ages of puberty and marriage, and breastfeeding duration. Acute undernutrition is related to lower birthrates. Examples of acute undernutrition are famine and food shortages due to war, crop failures, and poor hunting conditions. Births increase after the food shortage is resolved, but it can take up to a year for menstrual cycles to return to normal. Other factors affecting fertility are discussed: body fat, weight loss, exercise, certain dietary patterns such as vegetarianism, preconception iron status, and high caffeine and alcohol intakes. Nutritional factors affecting male fertility include weight loss of 10-15% below normal, low zinc status, lack of antioxidant nutrients, high level of alcohol intake, and exposure to heavy metals.

V. Nutrition During the Periconceptional Period

Table 2.6 (p. 61) details periconceptional nutritional exposures that may affect the growth and development of the embryo and fetus. Insufficient maternal folate stores may increase the baby's risk of neural tube defects as well as other physical defects. Low iron stores have been shown to increase the baby's risk of being delivered prematurely and having low iron stores.

VI. Recommended Dietary Intake and Healthy Dietary Patterns for Preconceptional Women

Nutritionally balanced meals for preconceptional women can be designed with the help of USDA's ChooseMyPlate.gov dietary planning tools. Examples of such meal plans are summarized in Table 2.8 (p. 64) and Table 2.9 (p. 64).

VII. Influence of Contraceptives on Preconceptional Nutrition Status

Hormonal contraceptives have implications for the human body; some contraceptives (like Depo-Provera) are associated with weight gain, whereas other contraception methods can alter blood lipid levels and glucose metabolism. Hormonal contraception for males exists but is not currently available because it still needs to be approved.

VIII. Model Preconceptional Health and Nutrition Programs

WIC is a USDA program designed to improve reproductive health (pp. 65). A program to decrease iron deficiency in Indonesia is an international example of improving preconception nutrition (p. 65). "Starting pregnancy in the best health status possible can make an important difference to reproductive outcomes" (p. 66), but it is not a guarantee for a perfect newborn.

IX. The Nutrition Care Process

The Nutrition Care Process is a standard nutrition care methodology developed by the Academy of Nutrition and Dietetics to serve as a guideline for the delivery of nutrition services (Table 2.10 on p. 67 summarizes the components of the Nutrition Care Process). Preconception services are tailored to the nutrition needs of women before pregnancy, and to the nutrition and reproductive health needs of men.

Internet Resources At-a-Glance

• Preconception Nutrition

- Medscape Ob/Gyn & Women's Health: <http://www.medscape.com/womenshealth>
- Women's Health: <http://www.womenshealth.gov/>
- The BabyCenter Company: www.babycenter.com

- Academy of Nutrition and Dietetics:
<http://www.eatright.org/resources/health/pregnancy/fertility-and-reproduction>
- **Public Food & Nutrition Programs**
 - WIC: <http://www.fns.usda.gov/wic/>
- **Nationwide Priorities & Nutritional Health**
 - Statistics – Centers for Disease Control/National Center for Health Statistics:
www.cdc.gov/nchs
- **Science of Nutrition**
 - Merck Manual of Diagnosis and Therapy:
<http://www.merckmanuals.com/professional/index.html>
 - National Library of Medicine (PubMed): www.ncbi.nlm.nih.gov/pubmed
- **Medscape Women's Health Journal**
 - This free-to-the-consumer website provides automatic updates on women's health, fertility, and contraception topics. You must, however, subscribe and enter a password. To begin, you must go to www.medscape.com. After registration, you can link to <http://www.medscape.com/womenshealth/journals> and access scientific and pharmaceutical literature and newspaper resources. Companies submit pre-publication abstracts to this site, i.e., before they are published in peer-reviewed journals.

Exploring the Internet: E-Trips

- Determine the amount of folic acid in the foods you ate in the last 24 hours. How does that compare with the recommendations for a male or female your age? To enter foods and obtain their folic acid content, use the online USDA search tool called, *What's In The Foods You Eat*, at: <http://www.ars.usda.gov/Services/docs.htm?docid=17032>. Go to the Fast Food Facts website <http://fastfoodnutrition.org/> to obtain nutrient information for foods served at fast food restaurants. Identify a typical meal you might order and obtain the amount of folic acid in your favorite fast-food order.
- Use the BabyCenter Company online address (www.babycenter.com) to obtain a recommendation about preconceptional nutrition. Evaluate their consumer advice with the science presented in this chapter or in the literature. Record the search terms you used to gather the information in both the scientific literature and the online website. Which of the terms that you used are ones that you think a consumer might use?
- Use the National Library of Medicine (NLM) MeSH (i.e., Medical Subject Heading or MeSH) database available under the heading "More Resources" found on the right-hand side of the PubMed website (www.ncbi.nlm.nih.gov/pubmed). Enter the following terms from the chapter and report if the textbook term is the same as the search term for finding current research on preconceptional nutrition topics. Also report the NLM definition for the term and the year the term was added as an official "MeSH term." Finally, identify some possible terms to use when searching for "contraception."

Body mass index

An indicator of body density as determined by the relationship of BODY WEIGHT to BODY HEIGHT. BMI = weight (kg)/height squared (m²). BMI correlates with body fat (ADIPOSE TISSUE). Their relationship varies with age and gender. For adults, BMI falls into these categories: below 18.5 (underweight); 18.5-24.9 (normal); 25.0-29.9 (overweight); 30.0 and above (obese).

Year introduced: 1990

Fertility

*The capacity to conceive or to induce conception. It may refer to either the male or female.
No year of entry noted.*

Infertility

*Inability to reproduce after a specified period of unprotected intercourse. Reproductive sterility is permanent infertility.
Year introduced: 1983*

Subfertility

There is no MeSH term as written; instead, MeSH displays the term "fertility".

Prostaglandins

*A group of compounds derived from unsaturated 20-carbon fatty acids, primarily arachidonic acid, via the cyclooxygenase pathway. They are extremely potent mediators of a diverse group of physiological processes.
Year introduced: 1966 (1963); Note, there are 18 prostaglandin types that are acceptable MeSH search terms.*

Neural tube defects

*Congenital malformations of the central nervous system and adjacent structures related to defective neural tube closure during the first trimester of pregnancy generally occurring between days 18-29 of gestation. Ectodermal and mesodermal malformations (mainly involving the skull and vertebrae) may occur as a result of defects of neural tube closure.
(From Joynt, Clinical Neurology, 1992, Ch55, pp31-41)
Year introduced: 1979*

Contraception:

*Prevention of CONCEPTION by blocking fertility temporarily, or permanently (STERILIZATION, REPRODUCTIVE). Common means of reversible contraception include NATURAL FAMILY PLANNING METHODS; CONTRACEPTIVE AGENTS; or CONTRACEPTIVE DEVICES.
Year introduced: 1963*

Discussion Questions

- A. Distinguish between fecundity (biological capacity to bear children), infertility (lack of conception after one year of unprotected intercourse), and being subfertile.
 1. Discuss the main reasons for often-delayed conception in 18% of married couples in the U.S. (p. 51).
 2. Identify what helps and harms men and women who wish to have children; describe practices that support robust pregnancy outcomes. How can a comparison of reproductive health practices and outcomes among communities and nations be used to understand conceptional health? [Spot problems, identify trends, and prevent poor outcomes.]
- B. What makes nutritional aspects of reproduction different for males and females? Have students elaborate on any or all of the following statements:
 1. Hormones differ between males and females.
 2. Body composition, i.e. percent of body fat, differs between males and females.

3. Women carry the developing fetus through gestation whereas males do not.
 4. Women are born with a full complement of eggs that runs out around menopause whereas men can produce sperm indefinitely, even if number or viability of sperm declines.
- C. What are the relationships between body weight and conception? Discuss the national health goals found in Healthy People 2020 (Table 2.1) as they affect conception.
1. Define a healthy weight range, using body mass index (found inside text cover). Would BMI change in a woman who was in her late forties and planning on becoming pregnant? That is, does age affect our perception of what a healthy weight range is? Why or why not?
 2. Definitions of what constitutes a healthy weight vary. The BMI is not a strong enough measure to yield consistent interpretations about optimal weight, although NIH has published national guidelines. Unlike the atomic clock, to which people around the world calibrate their computers and watches, the BMI is meant to be used as a general guide; in this case, for conception and optimal pregnancy outcome.
 3. Healthy weight is also a cultural issue. Perceptions of beauty and desirable body shape vary from culture to culture. A country or community where many people with various cultural backgrounds live has a more difficult time developing relevant population guidelines regarding a “healthy weight.”
 4. Obesity and underweight both decrease ability to conceive (Table 2.3). Weight loss of more than 10-15% of normal weight is related to infertility in men and women. To explain what 15% of normal weight means, point out that a 100-pound person would now weigh 85 pounds and a 150-pound person would now weigh 122.5 pounds (a decrease of several clothing sizes).
 5. Weight-related factors that impact fertility are summarized in Table 2.3, including negative energy balance, too little body fat, excessive body fat, anorexia nervosa, and bulimia nervosa. Pages 56 - 57 suggest that fertility is compromised when BMI is less than 20 and over 30.
 6. Summary: Evidence relating weight status to preconception nutrition suggests that a fairly broad range of body weights will support pregnancy.
- D. Why is it recommended that females who are at risk of cardiovascular disease or blood clots, and women with high blood pressure (p. 64) use non-hormonal methods of contraception?
- E. High levels of body fat lead to increased levels of leptin and estrogen; low levels of body fat decrease leptin and estrogen (p. 56 - 57). How do these high or low hormone levels affect fertility?
- F. Estrogen and progesterone prompt the endometrium to store glycogen and other nutrients during both the follicular and the luteal phases. Does this nutrient-storage function of estrogen and progesterone support fertility or fecundity? Elaborate.

Classroom Activities

- A. **Develop a one-page nutritional status assessment tool** (including a scoring system) for a fertility clinic. What measurements would you make and what questions would you ask men who seek to cure their infertility? What questions would you ask women? (Refer to Tables 2.3 and 2.6 for elaboration.)
- B. You are a consulting nutritionist with Women's Health Clinic and are asked to develop nutrition-focused, take-home literature to be used with oral contraceptives, contraceptive injections, implants, and mechanical devices (e.g., diaphragm). Pick one of the pharmaceutical or drug methods and **develop nutritional advice for women using that contraceptive method**. Compare this advice to what you would tell someone who is using a diaphragm. Be sure to include advice on foods to eat, such as a sample meal plan or food lists. (Refer to Tables 2.6, 2.7, 2.8, and 2.9 or ChooseMyPlate.gov; see also heart disease prevention in Chapter 17.)
- C. **Develop a "Healthy Sperm Diet"** for use by the health clinic on campus. Be sure to include some of the fast foods available on or near your campus. [Text, beginning on page 58, addresses adequate zinc, high level of antioxidants, light to moderate alcohol, clean arteries, controlled diabetes, seafood and avoidance of heavy metals such as mercury.]
- D. **Multi-part questions** (this one requires homework): Before discussion, assign students an online search:
 1. What can each one find out about the effectiveness of the herb black cohosh in treating menstrual disorders? Is the information they found referenced? What are the references used? Are any of the sites used linked to product sales? If so, give examples. How would a consumer know which advice can be trusted?
 2. Compile student answers (whiteboard, overheads) and discuss:
 - a. How did they devise a search strategy?
 - b. Review their findings, using each of the questions in their assignment.
 3. Summarize: If students were asked for advice regarding cohosh from their best friend, what would they suggest? What would you (their instructor) advise? What were the most credible online resources? Where could they go to verify information?
 4. How can the class apply this process to other herbal or new products?

Worksheet 2-1: Preconception Nutrition Counseling

Catherine decided to see a registered dietitian after watching a news story about the new 2006 CDC Preconception Health Initiative (p. 66), including the recommendation that each person should make a reproductive life plan. Currently 29 years old, she has been on oral contraceptives for 10 years. She would like to have children some day, possibly in her mid-thirties, after she has established her career. Her height is 5'6" and her weight is 175#. She considers herself fairly active, exercising for about 30 minutes three times per week. Due to being a busy professional, she admits to drinking close to 40 ounces of coffee most days and only occasionally drinks alcohol. Her personal health history includes iron-deficiency anemia at age 25, although she thinks this has resolved; her family history includes heart disease and type 2 diabetes; both of her parents are still living. No recent lab work is available.

Her questions for the dietitian are:

1. Should she change her method of contraception for nutrition or other health reasons?
2. Are there any risk factors for impaired fertility in her current health status?
3. What recommendations do you have to help her meet her long-term goal of having children someday?

Worksheet 2-2: Iron and Vitamin C Intake

As discussed in Chapter 2, iron status prior to pregnancy can be related to the outcomes of fertility and pregnancy (p. 58 - 59). How is your current dietary iron intake? Vitamin C-rich foods eaten in combination with iron-containing foods can increase the absorption of iron. How is your vitamin C intake? Use the USDA's Super Tracker tool (<http://www.choosemyplate.gov/supertracker-tools/supertracker.html>) to complete the following table with the foods and beverages you eat in 1 day.

[illegible]

- How do your intakes of vitamin C and iron compare with the DRI for your gender and age (see inside front cover of the text book)?
- What suggestions do you have for improving your intake of these nutrients?

CREATING A PROFILE

When any user (Instructor or Student) logs into Diet & Wellness Plus for the first time, they must create a profile, as illustrated in Figure 14, below.

The screenshot shows the 'Create Profile' page of the Diet & Wellness Plus application. The page has a dark blue header with the 'MindTap' logo and navigation links for 'INSTRUCTOR QA4', 'Customer Support', and 'Logout'. A sidebar on the right contains various icons including a search icon, a plus icon, an 'A-Z' index, and several social media and utility icons. The main content area is titled 'Create Profile' and includes a welcome message: 'Welcome to Diet & Wellness Plus. A profile is required to utilize the site.' The form contains several input fields and checkboxes: 'Name' (with a red asterisk) is set to 'Primary Profile'; 'Canadian Profile' is an unchecked checkbox; 'Birth Date' is set to 'August 21, 1993' with a calendar icon; 'Gender' is set to 'Male' in a dropdown menu; 'Height Feet' is set to '5' and 'Height Inches' is set to '6', both in dropdown menus; 'Weight' (with a red asterisk) is set to '100' in a text field; 'Smoker' and 'Strict Vegetarian/Vegan' are unchecked checkboxes. Below the form is a section titled 'Long Activity Questionnaire' with the first question: '1. Do you know your body fat percentage?'. The 'No' radio button is selected, and the 'Yes' radio button is unselected.

Figure 14 – Any user logging into Diet & Wellness Plus for the first time must create a new profile.

Enter a name for your profile (if you wish to change it from its default value - you don't have to) and select your date of birth.

MindTap™ INSTRUCTOR QA4 | Customer Support | Logout ?

Diet & Wellness Plus Download X

Create Profile

Welcome to Diet & Wellness Plus. A profile is required to utilize the site.

Name * Instructor's Profile

☐ Canadian Profile

Birth Date August 22, 1993

Gender Male

Height Feet 5

Height Inches 6

Weight * 100

☐ Smoker

☐ Strict Vegetarian/Vegan

Long Activity Questionnaire

Calendar: Aug 1960

Su	Mo	Tu	We	Th	Fr	Sa
				3	4	5
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Figure 15 – Selecting your date of birth in the calendar.

Enter your height and weight and answer all of the questions in the Long Activity Questionnaire.

MindTap™ INSTRUCTOR QA4 | Customer Support | Logout ?

Diet & Wellness Plus Download

Create Profile

Welcome to Diet & Wellness Plus. A profile is required to utilize the site.

Name * Instructor's Profile

☐ Canadian Profile

Birth Date May 31, 1960

Gender Male

Height Feet 6 ft.

Height Inches 2 inches

Weight * 180 lbs.

☐ Smoker

☐ Strict Vegetarian/Vegan

Long Activity Questionnaire

1. Do you know your body fat percentage?

☒ No
☐ Yes

2. What type of occupation do you have?

Sedentary desk occupation
Standing/moving occupation
Active occupation

3. How many hours per week do you perform this occupation? *

0 hrs

Figure 16 – Enter your height and weight and answer all of the questions in the Long Activity Questionnaire.

After completing your profile, click on the Submit button.

The screenshot displays the 'Diet & Wellness Plus' form on the MindTop website. The form contains the following questions and inputs:

- 2. What type of occupation do you have?**
Sedentary desk occupation (dropdown menu)
- 3. How many hours per week do you perform this occupation? ***
40 hrs (text input)
- 4. How much time do you spend on leisure time and activities of daily living in an average week?**
3+ hrs (dropdown menu)
- 5. How would you rate your walking pace?**
Steady (2-3 mph) (dropdown menu)
- 6. How much time do you spend performing light physical exercise in an average week?**
3+ hrs (dropdown menu)
- 7. How much time do you spend performing moderate physical exercise in an average week?**
2-3 hrs (dropdown menu)
☐ I consider myself an elite athlete.
- 8. How much time do you spend performing high-intensity physical exercise in an average week?**
1-2 hrs (dropdown menu)

At the bottom of the form, there are two buttons: 'Reset' and 'Submit'. The 'Submit' button is highlighted with a green rectangular box.

Figure 17 – Click the Submit button.