SUBJECT ID:				SUBJECT INITIALS:			VISIT DATE:					
							D	D	M	M	Y	Y

TRINIDAD STUDY VISIT 1

CASE REPORT FORM

Prevalence of Polycystic Ovary Syndrome in Trinidad and Tobago

Study reference number: CREC-SA.1723/08/2022

INSTITUTION: The University of the West Indies

PRINCIPAL INVESTIGATOR: Prof. Ricardo Azziz, Ms. Sasha Ottey, Dr. Venkatesan Sundaram, Dr. Brian Cockburn & Dr. Stephanie Mohammed.

I am confident that the information supplied in this case report form is complete and accurate data. I confirm that the study was conducted in accordance with the study protocol, protocol amendments, and that written informed consent was obtained prior to any study procedures.

Investigator's Signature: ____________________

Date of signature:

D	D	M	M	Y	Y	Y	Y

MINIMUM REQUIRED INFORMATION 1

CONFIDENTIAL DRAFT

1. Date of visit:

D	D	M	M	Y	Y	Y	Y

2. Age at first visit: ________ Yr ☐ Don't know

3. Height (<u>self-reported</u>): ________ Cm ☐ Don't know

4. Weight (<u>self-reported</u>): ________ Kg ☐ Don't know

5. What is the highest level of education you have completed?

- ☐ No Educ.
- ☐ Primary
- ☐ Secondary
- ☐ Tertiary
- ☐ Post - vocational

6. Is participant currently working? ☐ Yes, complete below ☐ No (why)

7. Occupation

- ☐ 1 - Managerial
- ☐ 2 - Technicians and Professionals
- ☐ 3 - Clerical/secretary
- ☐ 4 - Services
- ☐ 5 - Sales/Market woman
- ☐ 6 – Self-Employed Farming
- ☐ 7 - Employee Farming
- ☐ 8 - Skilled manual labor
- ☐ 9 - Unskilled manual labor

COMPLETED BY: **SIGNATURE:**

SUBJECT ID:					SUBJECT INITIALS:				VISIT DATE:					
TRINIDAD STUDY VISIT 1									D	D	M	M	Y	Y

CONTACT INFORMATION

1. Street address

house number

____

____

____

Other district zone ______________________________

____

3. How long been living there? _______ years

4. Telephone numbers (including area code):

Cell ______________________________

Home ______________________________

Work ______________________________

5. E-mail: ______________ @ ______________

6. Emergency contact:

Name: ______________________________

Relationship to participant: ______________________________

____

Telephone number 1: ______________________________

Telephone number 2: ______________________________

CONFIDENTIAL DRAFT

SUBJECT ID:	SUBJECT INITIALS:	VISIT DATE:
		D D M M Y Y

TRINIDAD STUDY VISIT 1

SOCIO - DEMOGRAPHIC INFORMATION 1

1. Date of birth ☐☐☐☐ (M M Y Y)

2. Ethnic Group (see below): ☐ Patient

Ethnicity group codes:

1 East Indian
2 African
3 Asian
4 Mixed
5 Other

3. Religion:

- ☐ Anglican
- ☐ Catholic
- ☐ Methodist
- ☐ Presbyterian
- ☐ Pentecostal/Charismatic
- ☐ Other Christian ☐ Other
- ☐ Islam
- ☐ Traditional/Spiritualist
- ☐ Hindu
- ☐ No Religion

4. Current marital status?

- ☐ Single
- ☐ Married
- ☐ Cohabitation
- ☐ Would rather not say
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

CONFIDENTIAL DRAFT

5. Participant's monthly income (in TT)?

CATEGORY

- ☐ Under 5,000
- ☐ 5,000 – 10,000
- ☐ 10,000 – 15,000
- ☐ 15,000 – 20,000
- ☐ 20,000 – 25,000
- ☐ ≥ 26,000

COMPLETED BY: **SIGNATURE:**

SUBJECT ID:	SUBJECT INITIALS:	VISIT DATE:

TRINIDAD STUDY VISIT 1 — D D M M Y Y

SOCIO - DEMOGRAPHIC INFORMATION 2

11. Has the participant ever smoked or used tobacco products? ☐ **Yes** ☐ **No**

SOCIO - DEMOGRAPHIC INFORMATION 3

12. Does the participant consume alcohol? ☐ **Yes (complete below)** ☐ **No (go to 14)**

____

13. Does the participant consume recreational drugs? ☐ None ☐ Occasionally ☐ Daily

☐ Specify ____________________

SOCIO - DEMOGRAPHIC INFORMATION 4

14. How many minutes does the participant usually walk outside home every day?

- ☐ less than 10 minutes
- ☐ 10-19 minutes
- ☐ 20-39 minutes
- ☐ 40-59 minutes
- ☐ ≥1 hour

CONFIDENTIAL DRAFT

15. How often does the subject do exercises? (works up a sweat with increased heart rate : aerobic, jogging, tennis, swimming)

- ☐ 1 day per week
- ☐ 2 days per week
- ☐ 3 days per week
- ☐ 4 days per week
- ☐ ≥5 days per week
- ☐ **None**

16. How strenuous is the subject's exercise?

- ☐ Mild (slow dancing, bowling, golf)
- ☐ Moderate (not exhausting: biking, treadmill, dancing)
- ☐ Strenuous (sweats and increased heart rate: aerobics, jogging) tennis,

SUBJECT ID:				SUBJECT INITIALS:			VISIT DATE:					

TRINIDAD STUDY VISIT 1 D D M M Y Y

MEDICAL HISTORY 1

Please check if the participant has had any of the following conditions in the past, or at present

1 Cardiac

- ☐ *High Blood Pressure*
- ☐ *Heart Attack*
- ☐ *Heart Murmur*
- ☐ *Irregular Heartbeat*
- ☐ *Mitral Valve Prolapse*
- ☐ *Peripheral Vascular Disease*
- ☐ *Stroke*
- ☐ *Other* ______

2 Endocrine

- ☐ *Diabetes/sugar problems*
- ☐ *Thyroid disease*
- ☐ *Bone loss*
- ☐ *High Cholesterol*
- ☐ *Steroid Use*
- ☐ *Other* ______

3 Respiratory

- ☐ *Asthma*
- ☐ *Chronic Cough*
- ☐ *Bronchitis*
- ☐ *Emphysema*
- ☐ *Other* ______

4 Neurologic

- ☐ *Spine/Back Injury*
- ☐ *Multiple Sclerosis*
- ☐ *Parkinson's*
- ☐ *Stroke*
- ☐ *Seizure Disorder/Epilepsy*
- ☐ *Other* ______

CONFIDENTIAL DRAFT

5 Gastrointestinal

- ☐ *Stomach Ulcers*
- ☐ *Irritable Bowel*
- ☐ *Constipation*
- ☐ *Diverticulitis*
- ☐ *Ulcerative colitis*
- ☐ *Crohn's Disease*
- ☐ Other ______

6 Bleeding Disorders

- ☐ *Chronic Aspirin Use*
- ☐ *History of Blood Clot*
- ☐ *Platelet Problem*
- ☐ *Blood Transfusion*
- ☐ *Other* ______

7 Genito-Urinary/Reproductive

- ☐ *Recurrent urine infections*
- ☐ *Kidney stones*
- ☐ *Difficulty getting pregnant*
- ☐ *Menopausal symptoms*
- ☐ *Other* ______

8 Cancer

- ☐ *Breast Cancer*
- ☐ *Lung Cancer*
- ☐ *Ovarian Cancer*
- ☐ *Thyroid Cancer*
- ☐ *Uterine Cancer*
- ☐ *Cervical Cancer*
- ☐ *Colon Cancer*
- ☐ *Other Cancer*

9 Musculo-skeletal

- ☐

10 Sleep Disturbance

- ☐ Difficulty falling asleep
- ☐ Mulitiple episodes of waking at night
- ☐ Excessive sleepiness during the day
- ☐ Other (snoring) (sleep ap form)

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11 Other

MEDICAL HISTORY 2

10. What has been the participant's weight change during adult life (do not include times of pregnancy or sickness)? How much?

(Mark only one)

- ☐ Weight has stayed about the same (within 5 kg)
- ☐ Steady weight gain
- ☐ Lost weight as an adult and kept it off
- ☐ Weight has gone up and down more than 5 kg.

11. Is the participant on any special diet?

☐ **Yes** ☐ **No**

Specify_____________________________

____

CONFIDENTIAL DRAFT

SUBJECT ID:	SUBJECT INITIALS:	VISIT DATE:

TRINIDAD STUDY VISIT 1 D D M M Y Y

SURGICAL HISTORY

1. Has participant had a hysterectomy?

☐ **Yes (complete below)** ☐ **No (go to 2)**

☐ Uterus ☐ Uterus + both ovaries

☐ Uterus + 1 ovary

Date: M M Y YM

Details ______

2. Has participant had any other surgeries (laproscopy, bariatric, removal of ovary?

☐ **Yes (complete below)** ☐ **No**

List other surgeries undergone, their date, and where it was performed, including date and details

		Date
1		M M Y Y
2		M M Y Y
3		M M Y Y
4		M M Y Y
5		M M Y Y

Continued, see attached ☐ **Yes** ☐ **No**

CONFIDENTIAL DRAFT

COMPLETED BY: **SIGNATURE:**

MEDICATIONS

3. Is participant currently or previously taking any hormonal contraceptive or metformin? ☐ **Yes (complete below)** ☐ **No**

	Name	No. of years used	Start Date *(MM/YY)*	Stop Date *(MM/YY)*	Still taking
☐	OCP "_______________"				☐
☐	Estrogens "___________"				☐
☐	Vaginal ring				☐
☐	Transdermal patch				☐
☐	Mirena IUD				☐
☐	Transdermal Implant				☐
☐	Injectable contraceptive				☐
☐	Metformin (_____ mg/day)				☐
☐	Infertility medications				☐
☐	Others				☐

CONFIDENTIAL DRAFT

4. Other medications, incl. vitamins & herbals? ☐ **Yes (list medications below)** ☐ **No**

	Medication and name	Dose	Start Date *(MM/YY)*	Stop Date *(MM/YY)*	Still taking
1					☐
2					☐
3					☐
4					☐
5					☐

Continued, see attached ☐ **Yes** ☐ **No**

SUBJECT ID:				SUBJECT INITIALS:			VISIT DATE:					

TRINIDAD STUDY VISIT 1 — D D M M Y Y

GYNECOLOGIC HISTORY 1

1. Age at 1st period? [ ][ ] Years

2. The subject's periods are:
- ☐ Regular
- ☐ Irregular (complete 5 & 6)
- ☐ Have stopped
- ☐ Never started

3. What is/was the average length of menstrual cycles? [ ][ ] Days* **(place a note)**

****Days between the start of one period and the start of the next***

4. What is/was the average No. menses cycles per year? [ ]

5. Date of last menstrual period: [ ][ ][ ][ ][ ][ ]
D D M M Y Y

CONFIDENTIAL DRAFT

GYNECOLOGIC HISTORY 2

5. Is the participant in menopause?
☐ **Yes (complete below)** ☐ **No**
☐ Natural menopause
☐ Surgical menopause

6. Does the participant have any menopausal symptoms? Which?
☐ **Yes (complete below)** ☐ **No**
☐ Hot flashes
☐ Night sweats
☐ Other ____________________

7. In total, how long has the participant been in menopause?
☐ Less than 1 year ☐ 1-2 years
☐ 2-4 years ☐ More than 4 years

8. How old was participant when she stopped having periods?
☐ Years

CONFIDENTIAL DRAFT

GYNECOLOGIC REVIEW 3

9. Is the participant sexually active?
☐ **Yes (complete below)** ☐ **No, never had sex**
☐ **No, but previously sexually active (answer below)**

How long? ____________________

10. Frequency of sex?
☐ More than 2 times a week
☐ Less than 2 times a week

11. Has the participant ever tried to become pregnant for more than 1 year, with no success?
☐ **Yes (go to 13)** ☐ **No (go to 24)**
☐ **Don't know (go to 13)**

12. Did the participant visit a doctor/clinic because of infertility?
☐ **Yes (go to 13)** ☐ **No (go to 24)**

13. Was the reason for infertility found? ☐ **Yes (go to 14)** ☐ **No (go to 15)**

14. What was the reason of infertility?

☐ Ovulation/menstruation problem
☐ Hormonal problem
☐ PCOS
☐ Pelvic infection
☐ Premature menopause
☐ Tubes/uterus problem
☐ Endometriosis
☐ Problem with partner
☐ Older age
☐ Don't know
☐ Other problem
*Specify*______________________

GYNECOLOGIC REVIEW 4

15. How many pregnancies did the participant have? [ ][ ]

16. How old was the participant at the end of her first pregnancy? [ ] years

CONFIDENTIAL DRAFT

17. How old was the participant at the end of her last pregnancy? [ ] years

18. № of live birth(s) [ ][ ]

19. № of stillbirth(s) [ ][ ]

20. № of ectopic pregnancies [ ][ ]

21. № of miscarriages [ ][ ]

22. № of elective/induced abortion(s) [ ][ ]

SUBJECT ID:					SUBJECT INITIALS:				VISIT DATE:					

TRINIDAD STUDY VISIT 1 — D D M M Y Y

GYNECOLOGIC REVIEW 5		
23. Does the participant complain of acne?	☐ **Yes (<u>complete below</u>)** Age first noticed: _____ years	☐ **No**
24. Does the participant complain of scalp hair loss?	☐ **Yes (<u>complete below</u>)** Age first noticed: _____ years	☐ **No**
25. In the below figure have participant mark how much scalp hair loss she has had.		

☐ Stage I ☐ Stage 2 ☐ Stage 3

COMPLETED BY: SIGNATURE:

SUBJECT ID:					SUBJECT INITIALS:				VISIT DATE:					

TRINIDAD STUDY VISIT 1 D D M M Y Y

GYNECOLOGIC REVIEW 9

26. Does the participant have excessive or unwanted hair growth?

☐ **Yes (complete below)** ☐ **No**

☐☐ Age first noticed

27. Does the participant remove excess body or facial hair (using electrolysis, lasers, shaving, creams, threading, etc.)?
If yes, on what body part?

☐ **Yes (complete below)*** ☐ **No**

☐ Upper lip ☐ Upper abdomen
☐ Chin ☐ Lower abdomen
☐ Chest ☐ Upper arms
☐ Upper back ☐ Thighs
☐ Lower back

**Not the lower legs or lower arms/forearms*

HYPERANDROGENIC FEATURES EVALUATION RECORD

Modified Ferriman-Gallwey Hirsutism Score

1 2 3 4
1 2 3 4
1 2 3 4
1 2 3 4
1 2 3 4

1 2 3 4
1 2 3 4
1 2 3 4
1 2 3 4

Circle each affected area

Total modified F-G score:

COMPLETED BY: **SIGNATURE:**

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GH-PEP STUDY VISIT 1								D	D	M	M	Y	Y

BECKS INVENTORY 1

28. Please complete below:

1.
   - 0 I do not feel sad.
   - 1 I feel sad
   - 2 I am sad all the time and I can't snap out of it.
   - 3 I am so sad and unhappy that I can't stand it.
2.
   - 0 I am not particularly discouraged about the future.
   - 1 I feel discouraged about the future.
   - 2 I feel I have nothing to look forward to.
   - 3 I feel the future is hopeless and that things cannot improve.
3.
   - 0 I do not feel like a failure.
   - 1 I feel I have failed more than the average person.
   - 2 As I look back on my life, all I can see is a lot of failures.
   - 3 I feel I am a complete failure as a person.
4.
   - 0 I get as much satisfaction out of things as I used to.
   - 1 I don't enjoy things the way I used to.
   - 2 I don't get real satisfaction out of anything anymore.
   - 3 I am dissatisfied or bored with everything.
5.
   - 0 I don't feel particularly guilty
   - 1 I feel guilty a good part of the time.
   - 2 I feel quite guilty most of the time.
   - 3 I feel guilty all of the time.
6.
   - 0 I don't feel I am being punished.
   - 1 I feel I may be punished.
   - 2 I expect to be punished.
   - 3 I feel I am being punished.
7.
   - 0 I don't feel disappointed in myself.
   - 1 I am disappointed in myself.
   - 2 I am disgusted with myself.
   - 3 I hate myself.
8.
   - 0 I don't feel I am any worse than anybody else.
   - 1 I am critical of myself for my weaknesses or mistakes.
   - 2 I blame myself all the time for my faults.
   - 3 I blame myself for everything bad that happens.
9.
   - 0 I don't have any thoughts of killing myself.
   - 1 I have thoughts of killing myself, but I would not carry them out.
   - 2 I would like to kill myself.
   - 3 I would kill myself if I had the chance.
10.
   - 0 I don't cry any more than usual.
   - 1 I cry more now than I used to.
   - 2 I cry all the time now.
   - 3 I used to be able to cry, but now I can't cry even though I want to.

COMPLETED BY: **SIGNATURE:**

BECKS INVENTORY 2

29. Please complete below (cont.):

11.
0 I am no more irritated by things than I ever was.
1 I am slightly more irritated now than usual.
2 I am quite annoyed or irritated a good deal of the time.
3 I feel irritated all the time.

12.
0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.

13.
0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions more than I used to.
3 I can't make decisions at all anymore.

14.
0 I don't feel that I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel there are permanent changes in my appearance that make me look unattractive
3 I believe that I look ugly.

15.
0 I can work about as well as before.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.

16.
0 I can sleep as well as usual.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than I used to and cannot get back to sleep.

17.
0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost anything.
3 I am too tired to do anything.

18.
0 My appetite is no worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worse now.
3 I have no appetite at all anymore.

19.
0 I haven't lost much weight, if any, lately.
1 I have lost more than five pounds.
2 I have lost more than ten pounds.
3 I have lost more than fifteen pounds.

BECKS INVENTORY 3

30. Please complete below (cont.):

20.
0 I am no more worried about my health than usual.
1 I am worried about physical problems like aches, pains, upset stomach, or constipation.
2 I am very worried about physical problems and it's hard to think of much else.
3 I am so worried about my physical problems that I cannot think of anything else.

21.
0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I have almost no interest in sex.
3 I have lost interest in sex completely.

SF-12

31. Please complete below (cont.):

1. In general, would you say your health is:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐1	☐2	☐3
3. Climbing **several** flights of stairs.	☐1	☐2	☐3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	NO
4. **Accomplished less** than you would like.	☐1	☐2
5. Were limited in the **kind** of work or other activities.	☐1	☐2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
6. **Accomplished less** than you would like.	☐1	☐2
7. Did work or activities **less carefully than usual.**	☐1	☐2

8. During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
10. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
11. Have you felt down-hearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

COMPLETED BY: **SIGNATURE:**

32. Please complete below: gyne history 1

1. On average, during the last three months, for how many days did your period last? (Please tick one box)

- □ Less than 3 days 0
- □ Between 3 and 7 days 0
- □ Between 8 and 10 days 0
- □ More than 10 days 0

2. On average, during the last three months, were your periods regular or irregular? (Please tick one box)

- □ Regular
- □ Irregular

3. On average, during the last three months, how many days were there from the first day of a period to the first day of the next period? (Please tick one box)

- □ Less than 21 days
- □ Between 21 and 35 days
- □ More than 35 days

4. On average, during the last three months, would you describe your periods as? (Please tick one box)

- □ Light
- □ Moderate
- □ Heavy
- □ Very Heavy

5. On average, during the last three months, for how many days of each period was the bleeding heavy? (Please tick one box)

- □ Not heavy
- □ Between 1 and 3 days
- □ Between 4 and 6 days
- □ Between 7 and 10 days
- □ More than 10 days

6. During the last three months, have you passed any clots of blood? (Please tick one box)

- □ Yes
- □ No

7. On average, during the last three months, have your periods been associated with any pain? (Please tick one box)

- □ No pain at all
- □ Slight pain
- □ Moderate pain
- □ Severe pain
- □ Very severe pain

8. On average, during the last three months, have you had any problems with soiling/staining any of the following because of your periods? (Please tick one box)

- □ Soiling/staining of your underclothes/undergarments
- □ Soiling/staining of your outer clothes/over garments
- □ Soiling/staining of your bed linen
- □ Soiling/staining of your upholstery

34. Please complete below (cont.):

9. On average, during the last three months, have your periods prevented you from carrying out your work, housework or other daily activities? (Please tick one box)

- □ No, not at all
- □ I could continue to work, but my work suffered
- □ Yes, usually with no more than one day with each period
- □ Yes, usually more than one day with each period

10. On average, during the last three months, have you been confined to bed with each period? (Please tick one box)

- □ No, not at all
- □ Yes, usually for part of one day
- □ Yes, usually for the whole of one day
- □ Yes, usually for more than one day

11. On average, during the last three months, have your leisure activities been affected by your heavy periods? (including sport, hobbies, social life)(Please tick one box)

- □ Not affected by heavy periods
- □ Mildly affected by heavy periods
- □ Moderately affected by heavy periods
- □ Severely affected by heavy periods
- □ Heavy periods have prevented any social life at all

12. On average, during the last three months, has your sex life been affected by your heavy periods? (Please tick one box)

- □ Not affected by heavy periods
- □ Mildly affected by heavy periods
- □ Moderately affected by heavy periods
- □ Severely affected by heavy periods
- □ Heavy periods prevented any sex life at all
- □ Does not apply

13. On average, during the last three months, how many tampons might you use on the heaviest day of your period? (Please tick one box)

- □ No tampons at all
- □ Between 1 and 5 tampons
- □ Between 6 and 10 tampons
- □ Between 11 and 15 tampons
- □ More than 15 tampons

14. On average, how many pads might you use on the heaviest day of your period? (Please tick one box)

- □ No pads at all
- □ Between 1 and 5 pads
- □ Between 6 and 10 pads
- □ Between 11 and 15 pads
- □ More than 15 pads

15. At any time during the last three months, did you require more than one form of protection at the same time (Not including mini pads or mini pant-liners)? (Please tick one box)

- □ No
- □ Tampon and pad together
- □ Two pads together
- □ Tampon and two pads together
- □ More protection than this (ie. disposable nappies, towels etc.)

Weight

Height

Waist

Hip

CONFIDENTIAL DRAFT