

Biospecimen Pre-Analytical Variables (BPV) Ovary Clinical Data Entry Form

PR-0009-F7

VER. 03.01

Effective Date: 03/11/2013

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BPV Case ID: _____

Affix BPV Case Barcode Label

Tissue Bank ID: _____

Completed by: _____

Date Form Was Completed: ___/___/_____
 (MM/DD/YYYY)

History of cancer in patient or blood relatives.

1. Does the participant have a history of prior malignancy?

- Select One:
 Yes (Enter details below)
 No
 Unknown

Description of diagnosis. Enter each previous cancer diagnosis in a separate row. Add any additional diagnoses to the comments section on the last page of this form.

When diagnosis was received. Date if known or how long ago.

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since diagnosis was received (in years) _____

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since diagnosis was received (in years) _____

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since diagnosis was received (in years) _____

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2. Enter participant's blood relatives who have had a history of cancer in a separate row. Add any additional diagnoses to the comments section on the last page of this form.	Type of cancer
<input type="checkbox"/> Aunt	
<input type="checkbox"/> Brother	
<input type="checkbox"/> Daughter	
<input type="checkbox"/> Father	
<input type="checkbox"/> Mother	
<input type="checkbox"/> Sister	
<input type="checkbox"/> Son	
<input type="checkbox"/> Uncle	
<input type="checkbox"/> Grandmother	
<input type="checkbox"/> Grandfather	
<input type="checkbox"/> Nephew	
<input type="checkbox"/> Niece	
<input type="checkbox"/> Other (specify) Specify other blood relative:	

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3. Does the participant have an immunosuppressive issue (HIV, organ transplant, steroid use, etc)?

Select One:

- Yes (Check all that apply below)
- No
- Unknown

Check all that apply:

- HIV
- Organ transplant
- Chronic systemic steroid use
- Other (specify)

Specify other immunosuppressive issue:

4. Has the participant received radiation therapy prior to surgery?

Select One:

- Yes – Describe radiation therapy below
- No
- Unknown

Describe each radiation therapy the participant received prior to surgery in a separate row. Add any additional radiation treatment to the comments section on the last page of this form.

When radiation therapy was received. Date if known or how long ago.

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since radiation therapy was received (in years) _____

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since radiation therapy was received (in years) _____

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5. Has the participant received chemotherapy prior to surgery?

- Select One:
 Yes (Describe chemotherapy below)
 No
 Unknown

Describe each chemotherapy the participant received prior to surgery in a separate row. Add any additional chemotherapy treatment to the comments section on the last page of this form.

When chemotherapy was received. Date if known or how long ago.

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since chemotherapy was received (in years) _____

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since chemotherapy was received (in years) _____

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6. Has the participant received immunotherapy prior to surgery?

- Select One:
- Yes (Describe immunotherapy below)
 - No
 - Unknown

Describe each immunotherapy the participant received prior to surgery in a separate row. Add any additional immunotherapy treatment to the comments section on the last page of this form.

When immunotherapy was received. Date if known or how long ago.

Date: ___/___/_____
(MM/DD/YYYY)

OR

Time since immunotherapy was received (in years) _____

Date: ___/___/_____
(MM/DD/YYYY)

OR

Time since immunotherapy was received (in years) _____

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7. Has the participant received hormonal therapy prior to surgery?

- Select One:
 Yes (Describe hormonal therapy below)
 No
 Unknown

Describe each hormonal therapy the participant received prior to surgery in a separate row. Add any additional hormonal therapy treatment to the comments section on the last page of this form.

When hormonal therapy was received. Date if known or how long ago.

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since hormonal therapy was received (in years) _____

Date: ___/___/_____
 (MM/DD/YYYY)

OR

Time since hormonal therapy was received (in years) _____

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Infectious Diseases

8. Has the participant been diagnosed with Hepatitis B?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown
9. Has the participant been diagnosed with Hepatitis C?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown
10. Has the participant been diagnosed with HIV?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown

Other (specify):

11. Does the participant have a history of repeatedly reactive screening assays for HIV-1 or HIV-2 antibodies regardless of the results of supplemental assays?	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Unknown
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Reproductive history

12. Has the participant ever been pregnant?	What is the total number of pregnancies?	What is the total number of live births?	What was the participant's age when her first biological child was born?
Select One: <input type="radio"/> Yes (If Yes, complete the next three columns) <input type="radio"/> No <input type="radio"/> Unknown			

13. Has the participant had any of these gynecological surgeries in the past?	Select One: <input type="radio"/> Hysterectomy <input type="radio"/> Unilateral oophorectomy <input type="radio"/> Neither hysterectomy nor oophorectomy <input type="radio"/> Unknown
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Hormonal birth control use. Document additional hormonal birth control use in the Comments section on the last page of this form.

14. Has the participant ever used hormonally based birth control?

- Select One:
- Current user (Enter details below)
 - Former user (Enter details below)
 - Never used
 - Unknown

Form of hormonal birth control

Duration (months)

Time since last usage (years)

Select One:

- Pill
- Injection
- IUD
- Patch
- Vaginal ring
- Other (specify)

Describe other hormonally based birth control:

Select One:

- Pill
- Injection
- IUD
- Patch
- Vaginal ring
- Other (specify)

Describe other hormonally based birth control:

General comment:

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Hormonal replacement therapy use. Document additional hormonal replacement use in the Comments section on the last page of this form.

15. Has the participant ever used hormone replacement therapy:

- Select One:
 Yes – Enter details below
 No
 Unknown

Form of hormone replacement therapy	Type of hormone replacement therapy	Duration (months)	Time since last usage (years)
Select One: <input type="radio"/> Pill <input type="radio"/> Patch <input type="radio"/> Cream <input type="radio"/> Unknown <input type="radio"/> Other (specify) Describe other hormone replacement therapy:	Select One: <input type="radio"/> Estrogen alone <input type="radio"/> Estrogen with progestin <input type="radio"/> Progestin alone <input type="radio"/> Testosterone <input type="radio"/> Unknown		
Select One: <input type="radio"/> Pill <input type="radio"/> Patch <input type="radio"/> Cream <input type="radio"/> Unknown <input type="radio"/> Other (specify) Describe other hormone replacement therapy:	Select One: <input type="radio"/> Estrogen alone <input type="radio"/> Estrogen with progestin <input type="radio"/> Progestin alone <input type="radio"/> Testosterone <input type="radio"/> Unknown		

General comment:

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16. Indicate participant's menopausal status:

Select One:

- Premenopausal: less than 6 months since LMP **AND** no prior bilateral oophorectomy **AND** not on estrogen replacement
- Perimenopausal: 6-12 months since last menstrual period
- Postmenopausal: prior bilateral oophorectomy **OR** more than 12 months since LMP with no prior hysterectomy
- Indeterminate: neither pre- nor post-menopausal

Alcohol history

17. Alcohol consumption:

- Lifelong non-drinker
- Alcohol consumption equal to or less than 2 drinks per day for men and 1 drink or less per day for women
- Alcohol consumption more than 2 drinks per day for men and more than 1 drink per day for women
- Consumed alcohol in the past, but currently a non-drinker
- Alcohol consumption history not available

18. Number of years participant has consumed more than 2 drinks per day for men and more than 1 drink per day for women:

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Tobacco smoking history

19. Tobacco smoking history:

- Select One:
- Lifelong non-smoker: less than 100 cigarettes smoked in lifetime
 - Current smoker: includes daily and non-daily smokers **(Enter details below)**
 - Current reformed smoker for more than 15 years **(Enter details below)**
 - Current reformed smoker for less than 15 years **(Enter details below)**
 - Smoking history not available

Tobacco smoking details: Complete if participant is a current or current reformed smoker.

Enter age at which the participant started smoking

Enter age at which the participant stopped smoking

On the days that the participant smoked, how many cigarettes did she/he usually smoke?

Number of pack years smoked. Pack years represent the lifetime tobacco exposure defined as number of cigarettes smoked per day times the number of years smoked divided by 20.

20. Was the participant exposed to second-hand smoke?

- Select One:
- No or minimal exposure to secondhand smoke
 - Yes **(Select exposure if known)**
 - Exposure to secondhand smoke in household during participant's childhood
 - Exposure to secondhand smoke in participant's current household
 - Exposure to secondhand smoke history not available

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Clinical FIGO stage

21. Clinical FIGO stage

Select One:

- Stage IA
- Stage IA1
- Stage IA2
- Stage IB
- Stage IB1
- Stage IB2
- Stage IIA
- Stage IIA1
- Stage IIA2
- Stage IIB
- Stage IIIA
- Stage IIIB
- Stage IVA
- Stage IVB
- Not Available

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Record Karnofsky score or Eastern Cancer Oncology Group (ECOG) score

22. Performance status scale recorded:

- Select One:
- Karnofsky score (**Complete Karnofsky Score section below**)
 - Eastern Cancer Oncology Group (**Complete ECOG score section below**)
 - Not recorded

Karnofsky score

- Select One:
- 100: asymptomatic
 - 80–90: symptomatic but fully ambulatory
 - 60–70: symptomatic but in bed less than 50% of the day
 - 40–50: symptomatic, in bed more than 50% of the day, but not bed ridden
 - 20–30: bed ridden

Eastern Cancer Oncology Group (ECOG) score

- Select One:
- 0: asymptomatic
 - 1: symptomatic but fully ambulatory
 - 2: symptomatic but in bed less than 50% of the day
 - 3: symptomatic, in bed more than 50% of the day, but not bed ridden
 - 4: bed ridden

23. Timing of score:

- Select One:
- Pre-operative
 - Pre-adjuvant therapy
 - Post adjuvant therapy
 - Unknown
 - Other (specify)
- Specify other timing of score:**

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24. Comments: