



University of Pennsylvania Smell Identification (UPSIT) Prescreening for Hyposmics for PPMI Prodromal Cohort

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Summary

The PPMI Central Olfactory Core provided eligible unaffected (Prodromal) participants a packet containing the consent (ICF) a coded Self Reporting Questionnaire (SRQ) and a 40-item (4 booklets) University of Pennsylvania Smell Identification Test (UPSIT)/ "Smell Identification Test" www.sensonics.com. The participant was instructed (written instructions) to complete the self report questionnaire to the best of their ability, and were **required to select a choice for** all 40 items/scents of the UPSIT even if no smell was identifiable. Participants returned the completed items in a seal pre-addressed envelope by local mail.

Method

Subject's complete the consent, SRQ, and UPSIT and returned via the USPS for review if the ICF, the de-identified SRQ and the UPSIT were provided to the centralized Olfactory Core for QC. The SRQ and UPSIT were date stamped received and QC'd for completeness. Acceptable responses for any of the 40 items on the smell test included circling, checking off, or selecting a response on the inner booklet. SRQ responses could be left unanswered, however, a DOB was required for the UPSIT percentile scoring and a "YES" to the PD question made the subject ineligible. If either of the two questions were missing answer(s) the Olfactory Core made an attempted to follow-up with the subject to obtain this information. All discrepancies were documented on a data clarification form in which the subject's response was noted.

SRQ data entry clarification:

Unanswered questions 2 - 6 of the SRQ follow this rule:

- If no answer is provided the response of "UNK" is entered in the database.

UPSIT score clarification:

Unanswered questions of the UPSIT follow these rules:

- When more than one answer is missing on the UPSIT all attempts are made to retrieve the missing responses by returning the booklet(s) to the subject.
- If one answer is missing or two answers are given for any one question of the 40 items on the UPSIT the rule is to provide the one answer.
 - The correct score is obtained manually using the UPSIT score key. These discrepancies are documented on a clarification form in which the correct answer is noted and passed along for processing.

Both the SRQ and UPSIT are considered acceptable for processing when no issues were present and consent is signed. Both documents were processed in parallel and kept together until data entry. When the SRQ and UPSIT are ready for processing they are double data entered in the OpenClinica (OC) study database to ensure the accuracy of the data.





The subject's percentile score is calculated within an Excel macro spreadsheet using the subject's reported gender (M or F), calculated age, and the total number of correct UPSIT items/scents. The maximum score for the items correct is ≤ 40 the minimum score is zero. The UPSIT percentile was calculated using the method described by Jennings *et al* Neurology 2014.

Per the PPMI protocol hyposmia was considered as $\leq 10^{\text{th}}$ percentile for age and gender based of the PARS scoring method referenced below.

These data sets are posted as "Olfactory UPSIT" and "Olfactory SRQ".

References

Sensonics, INC. manufacture of the University of Pennsylvania Smell Identification (UPSIT): <http://sensonics.com>

Imaging prodromal Parkinson disease: the Parkinson Associated Risk Syndrome Study. Jennings D1, Siderowf A2, Stern M2, Seibyl J2, Eberly S2, Oakes D2, Marek K2; PARS Investigators. Neurology. 2014 Nov 4;83(19):1739-46. Epub 2014 Oct 8.

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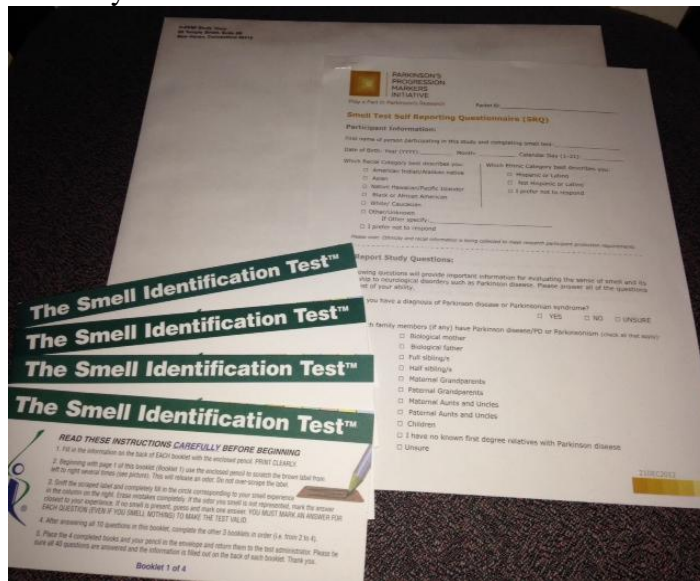


PARKINSON'S PROGRESSION MARKERS INITIATIVE

Play a Part in Parkinson's Research

APPENDIX 1: University of Pennsylvania Smell Identification Test (UPSIT)/ "Smell Identification Test" - Prescreening

Olfactory Packet:



UPSIT- Response tabs for 40 scents and an example of a question:

Example of UPSIT booklet response pages to be Faxed once completed

	10	9	8	7	6	5	4	3	2	1
Packet number A12345	a	a	a	a	a	a	a	a	a	a
	b	b	b	b	b	b	b	b	b	b
	c	c	c	c	c	c	c	c	c	c
	d	d	d	d	d	d	d	d	d	d

Booklet 1

	20	19	18	17	16	15	14	13	12	11
Packet number A12345	a	a	a	a	a	a	a	a	a	a
	b	b	b	b	b	b	b	b	b	b
	c	c	c	c	c	c	c	c	c	c
	d	d	d	d	d	d	d	d	d	d

Booklet 2

	30	29	28	27	26	25	24	23	22	21
Packet number A12345	a	a	a	a	a	a	a	a	a	a
	b	b	b	b	b	b	b	b	b	b
	c	c	c	c	c	c	c	c	c	c
	d	d	d	d	d	d	d	d	d	d


Booklet 3

	40	39	38	37	36	35	34	33	32	31
Packet number A12345	a	a	a	a	a	a	a	a	a	a
	b	b	b	b	b	b	b	b	b	b
	c	c	c	c	c	c	c	c	c	c
	d	d	d	d	d	d	d	d	d	d

Booklet 4

1. This odor smells most like:

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac



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PARKINSON'S PROGRESSION MARKERS INITIATIVE

Play a Part in Parkinson's Research

APPENDIX 2: PPMI Prodromal Self Reporting Questionnaire (SRQ) – Prescreening

<div><div>PARKINSON'S PROGRESSION MARKERS INITIATIVE <small>Play a Part in Parkinson's Research</small></div></div> <div>Packet ID: _____</div>	<div><div>PARKINSON'S PROGRESSION MARKERS INITIATIVE <small>Play a Part in Parkinson's Research</small></div></div> <div>Packet ID: _____</div>
<div>Smell Test Self Reporting Questionnaire (SRQ)</div> <div>Participant Information:</div> <div>First name of person participating in this study and completing smell test: _____</div> <div>Date of Birth: Year (YYYY) _____ Month: _____ Calendar Day (1-31): _____</div> <div>Which Racial Category best describes you: <input type="checkbox"/> American Indian/Alaskan native <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian/Pacific Islander <input type="checkbox"/> Black or African American <input type="checkbox"/> White/ Caucasian <input type="checkbox"/> Other/Unknown If Other specify: _____ <input type="checkbox"/> I prefer not to respond</div> <div>Which Ethnic Category best describes you: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> I prefer not to respond</div> <div><small>Please note: Ethnicity and racial information is being collected to meet research participant protection requirements</small></div> <div>Self Report Study Questions:</div> <div>The following questions will provide important information for evaluating the sense of smell and its relationship to neurological disorders such as Parkinson disease. Please answer all of the questions to the best of your ability.</div> <div><p>1. Do you have a diagnosis of Parkinson disease or Parkinsonian syndrome? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE</p><p>2. Which family members (if any) have Parkinson disease/PD or Parkinsonism (check all that apply): <input type="checkbox"/> Biological mother <input type="checkbox"/> Biological father <input type="checkbox"/> Full sibling/s <input type="checkbox"/> Half sibling/s <input type="checkbox"/> Maternal Grandparents <input type="checkbox"/> Paternal Grandparents <input type="checkbox"/> Maternal Aunts and Uncles <input type="checkbox"/> Paternal Aunts and Uncles <input type="checkbox"/> Children <input type="checkbox"/> I have no known first degree relatives with Parkinson disease <input type="checkbox"/> Unsure</p></div> <div>SRQ V1.0 21DEC2012</div>	<div>Self Report Study Questions page 2:</div> <div>The following questions will provide important information for evaluating the sense of smell and its relationship to neurological disorders such as Parkinson disease. Please answer all of the questions to the best of your ability.</div> <div><p>3. In the past year have you used laxatives or stool softeners regularly for 3 months or longer? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE</p><p>4. What is your usual number of bowel movements per day? <input type="checkbox"/> Less than once per day <input type="checkbox"/> Once every other day <input type="checkbox"/> Once per day <input type="checkbox"/> Two per day <input type="checkbox"/> Three per day <input type="checkbox"/> More than three per day</p><p>5. Have you noticed a decrease in your sense of smell over the last year? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE</p><p>6. Have you ever been told, or suspected yourself, that you seem to 'act out your dreams' while asleep (for example: punching, flailing your arms in the air, making running movements, etc)? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNSURE</p></div> <div>SRQ V1.0 21DEC2012</div>

