

|   |  |  |                                     |
|---|--|--|-------------------------------------|
| <b>NIDA-CPU- MARINOL - MJ -0001</b>                       |  | <b>Marinol – Marijuana Interaction Study</b> |                                     |
| Site ID: <u>990101</u>                                    |  | Subject ID: MJ ____ _                        | Study Day #: _____                  |
| Date: ____ / ____ / <u>200</u><br>m   m   d   d   y y y y |  | Completed as required <input type="radio"/>  | Not completed <input type="radio"/> |

Complete an AEs CRF if the result of the ECG evaluation corresponds to Abnormal, Significant.  
Record ECG data from assessment(s) performed on visit date recorded above.

| Screening <input type="radio"/>       |       |    |    |     |     |         |   |                                  |
|---------------------------------------|-------|----|----|-----|-----|---------|---|----------------------------------|
| Time of                               | Heart | PR | QT | QRS | R-R | QTc (F) | ECG Evaluation  | Specify abnormality as indicated |
| SCREENING<br>____ _                   |       |    |    |     |     |         | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                                  |
| Smoking Session <input type="radio"/> |       |    |    |     |     |         |   |                                  |
| BASELINE<br><br>0800 – 0845           |       |    |    |     |     |         | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                                  |
| ____ _<br>0905                        |       |    |    |     |     |         | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                                  |
| ____ _<br>0915                        |       |    |    |     |     |         | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                                  |
| ____ _<br>0930                        |       |    |    |     |     |         | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                                  |
| ____ _<br>0955                        |       |    |    |     |     |         | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                                  |

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|---|--|--|-------------------------------------|
| <b>NIDA-CPU- MARINOL - MJ -0001</b>                                   |  | <b>Marinol – Marijuana Interaction Study</b> |                                     |
| <b>Site ID: <u>990101</u></b>   |  | <b>Subject ID: MJ</b> _____                  | <b>Study Day #: _____</b>           |
| Date: <u>   </u> / <u>   </u> / <u>200</u><br>m   m   d   d   y y y y |  | Completed as required <input type="radio"/>  | Not completed <input type="radio"/> |

| Time of                       | Heart | PR | QT | QRS | R-R | QTc | ECG Evaluation  | Specify abnormality as |
|-------------------------------|-------|----|----|-----|-----|-----|---|------------------------|
| _____<br><b>1005</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1015</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1030</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1055</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1105</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1115</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |

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| <b>NIDA-CPU- MARINOL - MJ -0001</b>                                   |  | <b>Marinol – Marijuana Interaction Study</b> |  |                                     |
| Site ID: <u>990101</u>  |  | Subject ID: MJ _____                         |  | Study Day #: _____                  |
| Date: <u>    </u> / <u>    </u> / <u>200</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/>  |  | Not completed <input type="radio"/> |

| Time of                       | Heart | PR | QT | QRS | R-R | QTc | ECG Evaluation  | Specify abnormality as |
|-------------------------------|-------|----|----|-----|-----|-----|---|------------------------|
| _____<br><b>1130</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1155</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1300</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1400</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |
| _____<br><b>1500</b><br>_____ |       |    |    |     |     |     | <input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Abnormal, Significant<br><input type="radio"/> Not done |                        |

**Comments/ State reasons why not done:**

|                     |   |
|---------------------|---|
| Completed by: _____ | Date: <u>    </u> / <u>    </u> / <u>200</u><br>m m    d d    y y y y |
|---------------------|---|

|   |  |  |
|---|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>990101</u></b>                       | <b>Subject ID: MJ _____</b>                        |  |
| <b>Ongoing collected data through-out the study</b> | <b>Completed as required <input type="radio"/></b> | <b>Not completed <input type="radio"/></b> |

**Record all AEs on this form. Please complete data for each AE on a separate line. If an AE is evaluated as serious (SAE), please also complete the SAE Source Document. If the AE is continuing at study follow-up, the stop date may be left blank.**

**Has the participant experienced any AEs while participating in this study?**     Yes     No  
 If yes, please list all AEs and the corresponding data below:

| Adverse Event Name/Description | Start Date    | Stop Date     | Severity | Relationship to study agent | Actions Taken | Outcome | Serious (SAE)   |
|--------------------------------|---------------|---------------|----------|-----------------------------|---------------|---------|---|
|                                | _/_/___/_____ | _/_/___/_____ |          |                             |               |         | <input type="radio"/> Yes<br><input type="radio"/> No |
|                                | _/_/___/_____ | _/_/___/_____ |          |                             |               |         | <input type="radio"/> Yes<br><input type="radio"/> No |
|                                | _/_/___/_____ | _/_/___/_____ |          |                             |               |         | <input type="radio"/> Yes<br><input type="radio"/> No |
|                                | _/_/___/_____ | _/_/___/_____ |          |                             |               |         | <input type="radio"/> Yes<br><input type="radio"/> No |
|                                | _/_/___/_____ | _/_/___/_____ |          |                             |               |         | <input type="radio"/> Yes<br><input type="radio"/> No |

|  |  |  |  |
|--|--|--|--|
| <p><b>Severity Codes</b></p> <p>1 = Mild<br/>2 = Moderate<br/>3 = Severe</p> | <p><b>Relationship Codes</b></p> <p>1 = Definitely<br/>2 = Probably<br/>3 = Possibly<br/>4 = Remotely<br/>5 = Definitely Not<br/>6 = Unknown</p> | <p><b>Actions Taken Codes</b></p> <p>1 = No Action<br/>2 = Study agent discontinued permanently<br/>3 = Study agent discontinued temporarily<br/>4 = Reduced dose study agent<br/>5 = Increased dose study agent<br/>6 = Delayed dose study agent<br/>7 = Continued Dose<br/>8 = Unknown</p> | <p><b>Outcome Codes</b></p> <p>1 = Recovered/resolved<br/>2 = Recovering/resolving<br/>3 = Not recovered/not resolved<br/>4 = Recovered/resolved with sequelae<br/>5 = Fatal<br/>6 = Unknown</p> |
|--|--|--|--|

**Investigator’s signature:** \_\_\_\_\_ **Date:** \_\_\_/\_\_\_/200\_\_\_  
m m d d y y y y

|   |  |  |
|---|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  | <b>Subject ID: MJ</b> _____                        | <b>Study Day #: _____</b>                  |
| <b>Date:</b> _____ / _____ / <b>2 0 0</b><br><small>m m d d y y y y</small> | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

Complete blood level of analyte (quantity) and unit of measurement below. If other units are used instead of the standard unit, specify the unit as appropriate and cross out the standard unit. Indicate whether each measurement is Normal (within laboratory normal limits), Abnormal (outside of laboratory normal limits but not clinically significant), Abnormal Significant (outside laboratory normal limits and clinically significant), or Not Done. Provide comments for any significantly abnormal values below.

| Analyte                             | Standard |  |                       |                       |                       |                       |                       |
|-------------------------------------|----------|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Alkaline Phosphatase                | U/L      |  | <input type="radio"/> |
| Bicarbonate                         | mEq/L    |  | <input type="radio"/> |
| Chloride                            | mEq/L    |  | <input type="radio"/> |
| Gamma Glutamyl-transpeptidase (GGT) | U/L      |  | <input type="radio"/> |
| Magnesium                           | mEq/L    |  | <input type="radio"/> |
| Potassium                           | mEq/L    |  | <input type="radio"/> |
| SGOT/AST                            | U/L      |  | <input type="radio"/> |
| SGPT/ALT                            | U/L      |  | <input type="radio"/> |
| Sodium                              | mEq/L    |  | <input type="radio"/> |
| Total Bilirubin                     | mg/dL    |  | <input type="radio"/> |

**Provide comments for any Abnormal Significant value(s), or state reason Not Done:**

  
  
  
  

|                     |  |
|---------------------|--|
| Completed by: _____ | Date: _____ / _____ / <b>2 0 0</b><br><small>m m d d y y y y</small> |
|---------------------|--|

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|---|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                          |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                            |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date : _____ / _____ / <u>2 0 0</u></b><br>m m d d y y y y |  | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Time interval   | Time of Blood | Time interval  | Time of Blood |
|---|---------------|--|---------------|
| <b>08:00</b><br>Prior first capsule for<br>trough THC levels<br>(Study Part 2/Days 4, 6, 8) | _____         | <b>11:15</b><br>Baseline PK<br>(Smoking Session)                   | _____         |
| <b>09:55</b><br>Baseline PK<br>(Smoking Session)  | _____         | <b>11:25</b><br>Baseline PK<br>(Smoking Session)                   | _____         |
| <b>10:05</b><br>Baseline PK<br>(Smoking Session)  | _____         | <b>11:40</b><br>Baseline PK<br>(Smoking Session)                   | _____         |
| <b>10:15</b><br>Baseline PK<br>(Smoking Session)  | _____         | <b>11:55</b><br>Baseline PK<br>(Smoking Session)                   | _____         |
| <b>10:25</b><br>Baseline PK<br>(Smoking Session)  | _____         | <b>13:00</b><br>Baseline PK<br>(Smoking Session)                   | _____         |
| <b>10:40</b><br>Baseline PK<br>(Smoking Session)  | _____         | <b>14:00</b><br>Baseline PK<br>(Smoking Session)                   | _____         |
| <b>10:55</b><br>Baseline PK<br>(Smoking Session)  | _____         | <b>16:00</b><br>For peak THC levels<br>(Study part 2/Days 4, 6, 8) | _____         |
| <b>11:05</b><br>Baseline PK<br>(Smoking Session)  | _____         |  |               |

**For PK assessments during smoking sessions in both Study Parts 1 and 2, an intravenous catheter will be inserted prior to the start. Blood specimen (5 mL) will be collected into heparinized tubes.**

**During Study Part 2, blood specimen (5 mL) will be collected on Study Days 4, 6 and 8 for trough and peak THC levels:** Blood for trough levels will be collected just prior to the first capsule of the day at 0800 hours and blood for peak levels will be collected at approximately 1600 hours (two hours after the 1400 hour dose).

Completed by: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / 2 0 0  
m m d d y y y y

|   |  |   |                                     |
|---|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001   |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>   |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date: <u>   </u> / <u>   </u> / <u>2 0 0</u><br>m m       d d       y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

|                       |                       |  |
|-----------------------|-----------------------|--|
| Yes                   |                       |  |
| <input type="radio"/> | <input type="radio"/> |  |

**\*If participant was not enrolled, indicate reason below:**

- 1. Subject did not meet eligibility criteria
- 2. Failed to return to clinic
- 3. Declined study participation (specify in comments below)
- 4. Due to Medical Advice
- 5. Screen failure
- 6. Other, specify:

|                       |                       |   |
|-----------------------|-----------------------|---|
| Yes                   |                       | <b>Did the subject sign the informed consent to undergo screening for</b> |
| <input type="radio"/> | <input type="radio"/> |   |

|                             |                                |
|-----------------------------|--------------------------------|
| <b>Date consent signed:</b> | ___ / ___ / _____ (mm/dd/yyyy) |
|                             | ___ / ___ / _____ (mm/dd/yyyy) |

Note: Subject who signs the Informed Consent is considered "enrolled" in the study.

|                               |                                |                                    |
|-------------------------------|--------------------------------|------------------------------------|
| Yes                           |                                | <b>Was the subject randomized?</b> |
| <input type="radio"/>         | <input type="radio"/>          |                                    |
| <b>Date of Randomization:</b> | ___ / ___ / _____ (mm/dd/yyyy) |                                    |
|                               | ___ ___ ___                    |                                    |

**\*\*If participant was not randomized, indicate reason below:**

- 1. Failed to return to clinic
- 2. Declined study participation (specify in comments below)
- 3. Due to Medical Advice (Adverse Events)
- 4. Screen failure
- 5. Other, specify:

**Comments:**

Completed by: \_\_\_\_\_

Date:     /     / 2 0 0  
          m m       d d       y y y y

|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001                          |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>                            |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date : _____ / _____ / <u>2 0 0</u><br>m m d d y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

1. \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ **End of trial date** (mm/dd/yyyy) (last date any data was obtained on subject)

2. Status at end of trial (Select one)

- Subject completed study  
 Subject was a screen failure (not enrolled) (complete question 5 below)  
 Subject did not complete the study (early withdrawal) (complete question 6 below)

3. Did subject receive all protocol defined study treatments?

- Yes  
 No

Last date of study investigational treatment (mm/dd/ yyyy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

4. Did subject complete follow-up as prescribed in the protocol?

- Yes** (write F/U completion date below)       No       N/A

**Follow-up completion date** (mm/dd/yyyy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

5. If subject was a screening failure, indicate the **primary** reason for screening failure

- He/she did not meet study eligibility criteria  
 He/she did not complete screening process

6. If subject did not complete the study, indicate the **primary** reason for withdrawal

- Subject was determined after enrollment to be ineligible. (Provide comments)  
 Subject requested to withdraw. (Provide comments)  
 Subject experienced intercurrent illness, unrelated medical condition, or clinically significant adverse events, which, in the judgment of the investigator, prompted early termination. (If subject experienced adverse event(s), an Adverse Event Case Report Form(s) must be completed.) (Provide comments.)  
 Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)  
 Subject transferred to another treatment program (complete question 7 below)  
 Subject was incarcerated.  
 Subject became pregnant.  
 Subject developed sensitivity to study agent.  
 Subject was lost to follow-up.  
 Subject moved from area.  
 Subject died. (Complete Death Report CRF)  
 Subject can no longer attend clinic.  
 Subject is in a controlled environment.  
 Other (Provide comments)

7. If subject transferred to another treatment program, treatment program type (Select One)

- Methadone       Inpatient Detox or Treatment  
 LAAM       Therapeutic Community  
 Drug Free       Other, specify \_\_\_\_\_

8. Comments: \_\_\_\_\_  
 \_\_\_\_\_

Investigator's or designee's signature: \_\_\_\_\_ Date: \_\_\_\_\_

|   |  |  |
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| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                  | <b>Subject ID: MJ _____</b>                        |  |
| <b>Ongoing collected data through-out the study</b> | <b>Completed as required <input type="radio"/></b> | <b>Not completed <input type="radio"/></b> |

**Has the subject taken any medication during study participation?**

- Yes**
- No**

List all medications taken by the subject during study participation through the last follow-up visit. Indicate the name and reason the medication was being taken. Include quantity, dosage, frequency and route of administration data for each medication.

Please list the date the participant started the medication and the date the medication was discontinued.

|  |  |  |  |  |  |                     |
|--|--|--|--|--|--|---------------------|
|  |  |  |  |  |  |                     |
|  |  |  |  |  |  | Start ___/___/_____ |
|  |  |  |  |  |  | Stop ___/___/_____  |
|  |  |  |  |  |  | Start ___/___/_____ |
|  |  |  |  |  |  | Stop ___/___/_____  |
|  |  |  |  |  |  | Start ___/___/_____ |
|  |  |  |  |  |  | Stop ___/___/_____  |
|  |  |  |  |  |  | Start ___/___/_____ |
|  |  |  |  |  |  | Stop ___/___/_____  |

|   |   |   |  |   |  |  |  |
|---|---|---|--|---|--|--|--|
| <b>Dosage</b><br>CAP = capsule<br>g = gram<br>GR = grain<br>GTT = drop<br>GUM = Gum<br>LOP= Lollipop<br>LOT = Lotion/<br>ointment | <b>Dosage</b><br>ug = microgram<br>uL = microliter<br>mg = milligram<br>mL = milliliter<br>LOZ = Lozenge<br>Oz = ounce<br>PCH = Patch<br>PUF = puff | <b>Dosage</b><br>SPY = spray/squirt<br>SUP = suppository<br>TSP = teaspoon<br>TBS = tablespoon<br>IU = international<br>units | <b>Dosage</b><br>TAB = tablet<br>UNK = unknown<br>WFR = Wafer<br>OTH = other | <b>Frequency</b><br>ONCE = one dose<br>QD = once/day<br>BID = twice/day<br>TID = 3 times/day<br>QID = 4 times/day<br>QOD = every other day<br>PRN = as needed<br>UNK = unknown<br>OTH = other | <b>Route</b><br>PO = oral<br>TD = transdermal<br>INH = inhaled<br>IM = intramuscular<br>IV = intravenous | <b>Route</b><br>REC = rectal<br>VAG = vaginal<br>SL = sublingual<br>SQ = subcutaneous<br>AUR = auricular<br>IA = intra - articular | <b>Route</b><br>BUC = Buccal<br>NAS = nasal<br>IO = intraocular<br>OPT = Ophthalmic<br>TOP = Topical<br>UNK = unknown<br>OTH = other |
|---|---|---|--|---|--|--|--|

**Investigator's or designee's signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

|  |  |  |
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| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                               | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                                 | <b>Subject ID: MJ</b> _____                        | <b>Study Day #: _____</b>                  |
| <b>Date:</b> _____ / _____ / <b>2 0 0</b><br>m m    d d    y y y y | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Time Interval (24-hour clock)                      | Actual Time | Heart Rate | Blood Pressure |           |
|--|-------------|------------|----------------|-----------|
|  |             |            | Systolic       | Diastolic |
| 0845 – 0859 (-15 min to -1 min)<br><b>Baseline</b> |             |            |                |           |
| <b>First Cigarette @ 0900 approximately</b>        |             |            |                |           |
| 0905<br>(After 5 min of smoking cigarette)         |             |            |                |           |
| 0910<br>(After 10 min of smoking cigarette)        |             |            |                |           |
| 0915<br>(After 15 min of smoking cigarette)        |             |            |                |           |
| 0920<br>(After 20 min of smoking cigarette)        |             |            |                |           |
| 0925<br>(After 25 min of smoking cigarette)        |             |            |                |           |
| 0930<br>(After 30 min of smoking cigarette)        |             |            |                |           |
| 0935<br>(After 35 min of smoking cigarette)        |             |            |                |           |
| 0940<br>(After 40 min of smoking cigarette)        |             |            |                |           |
| 0945<br>(After 45 min of smoking cigarette)        |             |            |                |           |
| 0950<br>(After 50 min of smoking cigarette)        |             |            |                |           |
| 0955<br>(After 55 min of smoking cigarette)        |             |            |                |           |
| <b>Second Cigarette @ 1000 approximately</b>       |             |            |                |           |
| 1005<br>(After 5 min of smoking cigarette)         |             |            |                |           |
| 1010<br>(After 10 min of smoking cigarette)        |             |            |                |           |
| 1015<br>(After 15 min of smoking cigarette)        |             |            |                |           |
| 1020<br>(After 20 min of smoking cigarette)        |             |            |                |           |
| 1025<br>(After 25 min of smoking cigarette)        |             |            |                |           |
| 1030<br>(After 30 min of smoking cigarette)        |             |            |                |           |

|  |  |  |
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| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                               | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                                 | <b>Subject ID: MJ</b> _____                        | <b>Study Day #: _____</b>                  |
| <b>Date:</b> _____ / _____ / <b>2 0 0</b><br>m m    d d    y y y y | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Time Interval (24-hour clock)   | Actual Time | Heart Rate | Blood Pressure |           |
|---|-------------|------------|----------------|-----------|
|   |             |            | Systolic       | Diastolic |
| 1035<br>(After 35 min of smoking cigarette)   | _____       |            |                |           |
| 1040<br>(After 40 min of smoking cigarette)   | _____       |            |                |           |
| 1045<br>(After 45 min of smoking cigarette)   | _____       |            |                |           |
| 1050<br>(After 50 min of smoking cigarette)   | _____       |            |                |           |
| 1055<br>(After 55 min of smoking cigarette)   | _____       |            |                |           |
| <b>Third Cigarette @ 1100 approximately</b>   |             |            |                |           |
| 1105<br>(After 5 min of smoking cigarette)  | _____       |            |                |           |
| 1110<br>(After 10 min of smoking cigarette)   | _____       |            |                |           |
| 1115<br>(After 15 min of smoking cigarette)   | _____       |            |                |           |
| 1120<br>(After 20 min of smoking cigarette)   | _____       |            |                |           |
| 1125<br>(After 25 min of smoking cigarette)   | _____       |            |                |           |
| 1130<br>(After 30 min of smoking cigarette)   | _____       |            |                |           |
| 1135<br>(After 35 min of smoking cigarette)   | _____       |            |                |           |
| 1140<br>(After 40 min of smoking cigarette)   | _____       |            |                |           |
| 1145<br>(After 45 min of smoking cigarette)   | _____       |            |                |           |
| 1150<br>(After 50 min of smoking cigarette)   | _____       |            |                |           |
| 1155<br>(After 55 min of smoking cigarette)   | _____       |            |                |           |
| 1200<br>(After one hour of smoking cigarette)<br><small>*q15 min until come back to baseline or normal limits</small> | _____       |            |                |           |
| *1215   | _____       |            |                |           |
| *1230   | _____       |            |                |           |

|   |  |                                     |
|---|--|-------------------------------------|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>  | <b>Marinol – Marijuana Interaction Study</b> |                                     |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  | <b>Subject ID: MJ</b> _____                  | <b>Study Day #: _____</b>           |
| <b>Date:</b> _____ / _____ / <u>2 0 0</u><br><small>m m d d y y y y</small> | Completed as required <input type="radio"/>  | Not completed <input type="radio"/> |

| Time Interval (24-hour clock) | Actual Time | Heart Rate   | Blood Pressure |           |
|-------------------------------|-------------|--|----------------|-----------|
|                               |             |  | Systolic       | Diastolic |
| *1245                         |             |  |                |           |
| *1300                         |             |  |                |           |
| *1315                         |             |  |                |           |
| *1330                         |             |  |                |           |
| *1345                         |             |  |                |           |
| *1400                         |             |  |                |           |
| *1415                         |             |  |                |           |
| *1430                         |             |  |                |           |
| *1445                         |             |  |                |           |
| *1500                         |             |  |                |           |
| *1515                         |             |  |                |           |
| *1530                         |             |  |                |           |
| *1545                         |             |  |                |           |
| *1600                         |             |  |                |           |
| *1615                         |             |  |                |           |
| *1630                         |             |  |                |           |
| *1645                         |             |  |                |           |
| *1700                         |             |  |                |           |
| Completed by: _____           |             | Date: _____ / _____ / <u>2 0 0</u><br><small>m m d d y y y y</small> |                |           |

|   |  |   |                                     |
|---|--|---|-------------------------------------|
| NIDA-CPU- MARINOL – MJ - 0001   |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>   |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date: <u>   </u> / <u>   </u> / <u>2 0 0</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

Please complete this CRF only if the participant died during study participation

|  |  |
|--|--|
| 1. _____ / _____ / _____ (mm/dd/yyyy)  |  |
| 2a. <input type="radio"/> Yes<br><input type="radio"/> No<br><input type="radio"/> Unknown | 2b. If yes, is autopsy report <input type="radio"/> Yes<br><input type="radio"/> No<br><input type="radio"/> Unknown |
| 3. <input type="radio"/> Yes<br><input type="radio"/> No<br><input type="radio"/> Unknown  | If Yes, complete the next question (question/field #4)   |
| 4. _____<br>_____<br>_____<br>_____  |  |
| 5. _____<br>_____<br>_____   |  |

|                     |   |
|---------------------|---|
| Completed by: _____ | Date: _____ / _____ / <u>2 0 0</u><br>m m    d d    y y y y |
|---------------------|---|

|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU- Marinol - MJ - 0001  |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>990101</u>   |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date : <u>    </u> / <u>    </u> / <u>200</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

**DEMOGRAPHICS**

1. Gender: Male  Female

2. Date of Birth:      /      /       
                  m m    d d    y y y y

3. a. Ethnicity: \_\_\_\_\_  
 1. Spanish origin, Hispanic or Latino (go to item #3.b)  
 2. Not of Spanish origin, Hispanic or Latino (skip to question 4)  
 3. Unknown

b. Ethnicity specification: If Hispanic or Latino, write the ethnicity code described in the source document (3.b).

Specify: \_\_\_\_\_

4. Race: Write the race code described in the source document (4).

Specify: \_\_\_\_\_

**Employment / Support Status**

5. Highest Education Completed (GED = 12 years): a. Years \_\_\_\_\_ b. Months: \_\_\_\_\_  
 (If data not available enter "-1") (≤11months)

6. Usual Employment Pattern: a. Past 30 Days: \_\_\_\_\_ b. Past 3 Years: \_\_\_\_\_  
 (Use the codes described in the source document separated by commas)

7. Marital Status: \_\_\_\_\_  
 (Use the code described in the source document)

Completed by: \_\_\_\_\_

Date:      /      / 200  
          m m    d d    y y y y

|   |  |  |  |
|---|--|--|--|
| <b>NIDA-CPU – MARINOL - MJ - 0001</b>                                       |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date: _____ / _____ / <u>2 0 0</u></b><br><small>m m d d y y y y</small> |  | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Drug Name                             | Dates of History |  | Route of Administration | Amount Used |
|---------------------------------------|------------------|--|-------------------------|-------------|
|                                       |                  |  |                         |             |
| <input type="radio"/> Cocaine         |                  |  |                         |             |
| <input type="radio"/> Alcohol         |                  |  |                         |             |
| <input type="radio"/> Amphetamines    |                  |  |                         |             |
| <input type="radio"/> Opiates         |                  |  |                         |             |
| <input type="radio"/> Barbiturates    |                  |  |                         |             |
| <input type="radio"/> Methamphetamine |                  |  |                         |             |
| <input type="radio"/> Benzodiazepines |                  |  |                         |             |
| <input type="radio"/> Nicotine        |                  |  |                         |             |
| <input type="radio"/> PCP             |                  |  |                         |             |
| <input type="radio"/> Propoxyphene    |                  |  |                         |             |

**Use the suggested abbreviation codes below to complete the route of administration and units used fields:**

| Route of Administration  |  | Units Used  |  |  |
|--|--|---|--|--|
| 1= Oral<br>2= Nasal<br>3= Intravenous<br>4= Inhalation/Smoke<br>5= Topical Transdermal | 6= Intramuscular<br>7= Sublingual<br>8= Subcutaneous<br>9= Other | 1= Rocks<br>2= Grams<br>3= Milligrams<br>4= Teaspoons<br>5= Millimeters | 6= CC<br>7= Std beer drinks (12 oz.)<br>8= Std wine drinks (4 oz.)<br>9= Std hard liquor drinks (1.5 oz)<br>10= Joints or equivalent | 11= Cigarettes<br>12= Sticks of gum/Nicorette<br>13= Pinches of chew<br>14= Bags<br>15= Cigars |

Completed by: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / 2 0 0  
m m d d y y y y

|  |  |  |  |
|--|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                               |  | <b>Marinol – Marijuana Interaction Study</b>   |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                                 |  | <b>Subject ID: MJ _____ Study Day #: _____</b>   |  |
| <b>Date: _____ / _____ / <u>2 0 0</u></b><br>m m    d d    y y y y |  | <b>Completed as required <input type="radio"/> Not completed <input type="radio"/></b> |  |

Check “Yes” or “No” answer at your left.  
Check “N/A” at your right if the subject is male.

| <b>INCLUSION CRITERIA</b> |                       |  |                       |
|---------------------------|-----------------------|--|-----------------------|
| <b>Yes</b>                | <b>No</b>             | <b>CRITERIA</b>  | <b>N/A</b>            |
| <input type="radio"/>     | <input type="radio"/> | 1. Be man or woman between 18 and 45 years of age.   |                       |
| <input type="radio"/>     | <input type="radio"/> | 2. Have a DSM-IV diagnosis of current marijuana dependence as determined by SCID.  |                       |
| <input type="radio"/>     | <input type="radio"/> | 3. Be able to provide written informed consent.  |                       |
| <input type="radio"/>     | <input type="radio"/> | 4. Be willing and able to comply with study procedures including be able to participate in an in-patient study lasting 3-4 days (Study Part 1) or 12 days (Study Part 2).  |                       |
| <input type="radio"/>     | <input type="radio"/> | 5. Report regular marijuana use for the past year.   |                       |
| <input type="radio"/>     | <input type="radio"/> | 6. Provide 1 marijuana positive urine specimen within the 28-day screening period.   |                       |
| <input type="radio"/>     | <input type="radio"/> | 7. Be in general good health as determined by medical and psychiatric history, physical exam, vital signs, blood chemistries, hematology, medical urinalysis, infectious disease screen, current medication use, and ECG.  |                       |
| <input type="radio"/>     | <input type="radio"/> | 8. If female, have a negative pregnancy test and agree to use one of the following methods of birth control or be surgically sterile: oral contraceptives, patch, barrier (diaphragm or condom) with spermicide or condom only, intrauterine progesterone or non-hormonal contraceptive system, levonorgestrel implant, medroxyprogesterone acetate contraceptive injection, complete abstinence from sexual intercourse, hormonal vaginal contraceptive ring, and contraceptive sponge. | <input type="radio"/> |

| <b>EXCLUSION CRITERIA</b> |                       |   |                       |
|---------------------------|-----------------------|---|-----------------------|
| <b>Yes</b>                | <b>No</b>             | <b>CRITERIA</b>   | <b>N/A</b>            |
| <input type="radio"/>     | <input type="radio"/> | 1. Be using any prescription medication to treat a chronic medical condition.   |                       |
| <input type="radio"/>     | <input type="radio"/> | 2. Have a lifetime history of psychosis or current major psychiatric disorder treatment, or current schizophrenia or bipolar disorders.                                     |                       |
| <input type="radio"/>     | <input type="radio"/> | 3. Have cardiovascular problems such as tachyarrhythmia, angina pectoris, or hypertension.  |                       |
| <input type="radio"/>     | <input type="radio"/> | 4. Be pregnant or lactating.  | <input type="radio"/> |
| <input type="radio"/>     | <input type="radio"/> | 5. Have participated in any experimental study within 8 weeks (the nature of excluded studies may be discussed with NIDA investigators).                                    |                       |
| <input type="radio"/>     | <input type="radio"/> | 6. Have donated blood (>200 cc) in the past 4-weeks prior to clinic intake.   |                       |
| <input type="radio"/>     | <input type="radio"/> | 7. Have current physical dependence on any substance (including alcohol) other than nicotine or caffeine.   |                       |
| <input type="radio"/>     | <input type="radio"/> | 8. Have a positive urine drug screen or report using drugs during the 28-day screening period for the following drugs: cocaine, amphetamines, opiates, and benzodiazepines. |                       |

|   |  |   |                                     |
|---|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001                             |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>                               |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date: ____ / ____ / <u>2 0 0</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

| EXCLUSION CRITERIA (continuation) |                       |   |
|-----------------------------------|-----------------------|---|
| Yes                               | No                    | CRITERIA  |
| <input type="radio"/>             | <input type="radio"/> | 9. Have a history of seizure disorders of any etiology.   |
| <input type="radio"/>             | <input type="radio"/> | 10. Have clinically significant laboratory values (outside of normal limits), in the judgment of the investigator.  |
| <input type="radio"/>             | <input type="radio"/> | 11. Have a positive test for hepatitis B surface antigen (HBsAg), or positive serology for hepatitis C virus or human immunodeficiency virus-1 (HIV-1).   |
| <input type="radio"/>             | <input type="radio"/> | 12. Have sensitivity to marijuana, other cannabinoids, or sesame oil.   |
| <input type="radio"/>             | <input type="radio"/> | 13. Have received a medication that could interact adversely with study drug, with the time of administration of study drug and other medications based on the longest time interval of A, B or C, below:<br>A) Five half lives of other medication or active metabolite(s), whichever is longer<br>B) Two weeks<br>C) Interval recommended by other medication’s product labeling<br>Medications that fall into this category include: drugs that are tightly protein bound. |

**Note:** If any clinical findings and tests are positive or clinically significant, the subject will be notified of the test results and counseled to consult with his/her physician for evaluation and treatment.

| ELIGIBILITY                  |                       |  |
|------------------------------|-----------------------|--|
| Yes                          | No                    | Is the participant eligible for the study? |
| <input type="radio"/>        | <input type="radio"/> |  |
| Date eligibility determined: |                       | ____ / ____ / _____ (mm/dd/yyyy)           |

\_\_\_\_\_  
Investigator’s or designee’s signature

\_\_\_\_\_  
Date



|   |  |  |  |
|---|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>  |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>990101</u></b>   |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date: <u>    </u> / <u>    </u> / <u>200</u></b><br><small>m m d d y y y y</small> |  | <b>Completed as required <input type="radio"/></b> | <b>Not completed <input type="radio"/></b> |

Blood will be collected in a serum separation evacuated venous blood collection tube (e.g., Vacutainer™) and serum separated according to standard procedures. Qualitative analysis reporting positive/negative results will be performed for the analytes listed below:

| Analyte                     |                       |                       | *Not                  | Comments |
|-----------------------------|-----------------------|-----------------------|-----------------------|----------|
| Hepatitis B surface antigen | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |          |
| Hepatitis C virus antibody  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |          |
| HIV type 1                  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |          |

**\*State reason not done:**

|                     |  |
|---------------------|--|
| Completed by: _____ | Date: <u>    </u> / <u>    </u> / <u>200</u><br><small>m m d d y y y y</small> |
|---------------------|--|

NIDA-CPU- MARINOL - MJ 0001

Marinol – Marijuana Interaction Study

Site ID: 9 9 0 1 0 1

Subject ID: MJ \_\_\_\_ \_

By my signature below, I attest that I am the investigator listed on FDA Form 1572 and that I have reviewed and attest to the accuracy of all the data recorded on the CRFs herein and any Supplemental forms and supporting documents.

I understand that questions may result from the Sponsor's review of these case report forms. These questions may result from missing, unclear or incorrect entries. I understand that it will be necessary for me or my staff to make the appropriate corrections to the case report forms. By my signature below, I authorize my sub-investigator(s) or other approved personnel to make necessary corrections. I understand that I am ultimately responsible for any corrections made by my staff.

1. Date of signature: \_\_\_\_ / \_\_\_\_ / 200  
                                  m m    d d    y y y y

2. Principal Investigator's signature: \_\_\_\_\_

3. Principal Investigator's name: Louis Cantilena, Jr., M.D., Ph.D.

|   |  |  |  |
|---|--|--|--|
| <b>NIDA-CPU – MARINOL - MJ - 0001</b>                                       |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date: _____ / _____ / <u>2 0 0</u></b><br><small>m m d d y y y y</small> |  | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Use the suggested abbreviation codes below to complete the route of administration and units used fields: |  |   |  |  |
|---|--|---|--|--|
| Route of Administration   |  | Units Used  |  |  |
| 1= Oral<br>2= Nasal<br>3= Intravenous<br>4= Inhalation/Smoke<br>5= Topical Transdermal                    | 6= Intramuscular<br>7= Sublingual<br>8= Subcutaneous<br>9= Other | 1= Rocks<br>2= Grams<br>3= Milligrams<br>4= Teaspoons<br>5= Millimeters | 6= CC<br>7= Std beer drinks (12 oz.)<br>8= Std wine drinks (4 oz.)<br>9= Std hard liquor drinks (1.5 oz)<br>10= Joints or equivalent | 11= Cigarettes<br>12= Sticks of gum/Nicorette<br>13= Pinches of chew<br>14= Bags<br>15= Cigars |

| Marijuana Use   | Description    |       |                             |                         |                       |      |
|---|----------------|-------|-----------------------------|-------------------------|-----------------------|------|
| Dates of History  | First Time Use |       | Years of Use                |                         |                       |      |
|   | Month          | Year  | From                        |                         | # of Years            |      |
|   | ____           | ____  | Month                       | Year                    | Month                 | Year |
| <b>Route of Administration</b><br>(See abbreviation codes, above)   |                |       |                             |                         |                       |      |
| <b>Quantity Used in the Past 30 days</b><br>Specify units used (See abbreviation codes, above)<br>(See MJ Usage Calendar, page 2) |                |       | <b>Times of use</b>         | <b># of Days within</b> | <b>Total Quantity</b> |      |
|   | ____           | _____ | ____                        | ____                    | ____                  |      |
| <b>Frequency of Use in the Past 30 days</b><br>(See MJ Usage Calendar, page 2)  |                |       | Use within the Past 30 days |                         |                       |      |
|   | ____           |       | # of Days                   |                         |                       |      |
|   |                |       | ____                        |                         |                       |      |

|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU – MARINOL - MJ - 0001   |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>  |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date: <u>   </u> / <u>   </u> / <u>2 0 0</u><br><small>m m d d y y y y</small> |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

**MARIJUANA USAGE CALENDAR 2006-2007**

|   |  |
|---|--|
| Number of days to gather information: <u>30 days</u>                                      |  |
| Start Date (Day1): <u>   </u> / <u>   </u> / <u>   </u><br><small>m m d d y y y y</small> | End Date (yesterday): <u>   </u> / <u>   </u> / <u>   </u><br><small>m m d d y y y y</small> |

|       |     |     |     |     |       |     |     |
|-------|-----|-----|-----|-----|-------|-----|-----|
| 200_  | SUN | MON | TUE | WED | THURS | FRI | SAT |
| Month |     |     |     |     |       |     |     |
|       |     |     |     |     |       |     |     |
|       |     |     |     |     |       |     |     |
|       |     |     |     |     |       |     |     |

|       |     |     |     |     |       |     |     |
|-------|-----|-----|-----|-----|-------|-----|-----|
| 200_  | SUN | MON | TUE | WED | THURS | FRI | SAT |
| Month |     |     |     |     |       |     |     |
|       |     |     |     |     |       |     |     |
|       |     |     |     |     |       |     |     |
|       |     |     |     |     |       |     |     |

|                     |  |
|---------------------|--|
| Completed by: _____ | Date: <u>   </u> / <u>   </u> / <u>2 0 0</u><br><small>m m d d y y y y</small> |
|---------------------|--|

|   |  |   |                                     |
|---|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001                         |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>                           |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date: _____ / _____ / <u>2 0 0</u><br>m m d d y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

The patient circled in the corresponding Source Document the number which answers the symptom to the right that best describes how He/She felt: 0= Not at all; 1= Mild; 2= Moderate; 3= Severe

\*Time of Assessment: \_\_\_\_\_ (24-hour clock)

| Symptoms   |   |   |   |   | Individual |
|--|---|---|---|---|------------|
| 1) Craving   | 0 | 1 | 2 | 3 |            |
| 2) Irritability  | 0 | 1 | 2 | 3 |            |
| 3) Nervousness   | 0 | 1 | 2 | 3 |            |
| 4) Depression  | 0 | 1 | 2 | 3 |            |
| 5) Anger   | 0 | 1 | 2 | 3 |            |
| 6) Restlessness  | 0 | 1 | 2 | 3 |            |
| 7) Sleep Problems  | 0 | 1 | 2 | 3 |            |
| 8) Decreased Appetite  | 0 | 1 | 2 | 3 |            |
| 9) Strange Dreams  | 0 | 1 | 2 | 3 |            |
| 10) Headaches  | 0 | 1 | 2 | 3 |            |
| Sum of the individual item scores= Total Withdrawal Discomfort Score (WDS) |   |   |   |   | _____ WDS  |

**WDS:** Symptoms will be evaluated individually and by computing a total withdrawal discomfort score, which is the sum of the individual item scores.

**\*Time of assessment:** The MWSC is performed approximately the same time each day (1430 hours) during the withdrawal period. This is approximately 30 minutes after the 1400-hour dose of dronabinol/placebo

**Note:** The study physician is responsible for defining, in his/her best judgment, the relationship of an AE/SAE to the study drug/placebo.

|                     |   |
|---------------------|---|
| Completed by: _____ | Date: _____ / _____ / <u>2 0 0</u><br>m m d d y y y y |
|---------------------|---|

|  |  |                                     |
|--|--|-------------------------------------|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                       | <b>Marinol – Marijuana Interaction Study</b> |                                     |
| <b>Site ID: <u>990101</u></b>                              | Subject ID: MJ _____                         | Study Day #: _____                  |
| Date : _____ / _____ / <b>200</b><br>m m    d d    y y y y | Completed as required <input type="radio"/>  | Not completed <input type="radio"/> |

Complete Medical and Surgical History Below. Indicate medical history for each body system listed below by completing the bubble next to the appropriate response (Yes, No, Unknown).

If the response is Yes for any of the body systems, specify the medical problem and indicate if the condition excludes patient from study participation by completing the bubble in the left column.

**Medical History**

| Disorder |                              | No                    | Unknown               | *If Yes,              |                       |
|----------|------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|          |                              |                       |                       |                       |                       |
| 1        | Allergies                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2        | Allergies to drugs           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3        | Allergies: other<br>Specify: | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4        | Asthma                       | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5        | Cardiovascular               | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6        | Dermatologic                 | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7        | Endocrine                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8        | Gastrointestinal             | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9        | Genitourinary                | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10       | Head injury                  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 11       | HEENT                        | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 12       | Hematologic/ Lymphatic       | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 13       | Hepatic                      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 14       | Infectious Disease           | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 15       | Metabolic                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 16       | Musculoskeletal              | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 17       | Pulmonary                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 18       | Renal                        | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 19       | Reproductive system          | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

**Neurological History (Indicate history of disorders listed below)**

|    |                              |                       |                       |                       |                       |
|----|------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 20 | Epilepsy or Seizure Disorder | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 21 | Neurological Damage          | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 22 | Tourette's Syndrome          | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

**Psychiatric History (Indicate history of disorders listed below)**

|    |                           |                       |                       |                       |                       |
|----|---------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 23 | Anxiety or Panic Disorder | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
|----|---------------------------|-----------------------|-----------------------|-----------------------|-----------------------|

|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001                              |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>990101</u>                                     |  | Subject ID: MJ _____                        | Study Day #: _____                  |
| Date : _____ / _____ / <u>200</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

|    |  |                       |                       |                       |                       |                       |
|----|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 24 | Attention Deficit Hyperactivity Disorder | <input type="radio"/> |
| 25 | Bipolar Disorder                         | <input type="radio"/> |
| 26 | Homicidal Behavior                       | <input type="radio"/> |
| 27 | Homicidal Ideation                       | <input type="radio"/> |
| 28 | Major Depressive Disorder                | <input type="radio"/> |
| 29 | Psychotic Episodes                       | <input type="radio"/> |
| 30 | Schizophrenia                            | <input type="radio"/> |
| 31 | Suicidal Behavior                        | <input type="radio"/> |
| 32 | Suicidal Ideation                        | <input type="radio"/> |
| 33 | Violent Behavior                         | <input type="radio"/> |

Indicate other relevant medical history below. Provide specific details in the “Describe” section:

|    |  |                       |                       |
|----|--|-----------------------|-----------------------|
| 34 |  | <input type="radio"/> | <input type="radio"/> |
| 35 |  | <input type="radio"/> | <input type="radio"/> |
| 36 |  | <input type="radio"/> | <input type="radio"/> |

**Surgical History**

Has the subject had any major surgery?       Yes       No       Unknown

If the subject has had major surgery, provide surgery data below, including date of surgery (partial dates allowable). If date is unknown, indicate by completing the bubble in the right hand column.

|    | Type of Surgery | Surgery Date   | Date                  |
|----|-----------------|----------------|-----------------------|
| 37 |                 | ____/____/____ | <input type="radio"/> |
| 38 |                 | ____/____/____ | <input type="radio"/> |
| 39 |                 | ____/____/____ | <input type="radio"/> |
| 40 |                 | ____/____/____ | <input type="radio"/> |
| 41 |                 | ____/____/____ | <input type="radio"/> |
| 42 |                 | ____/____/____ | <input type="radio"/> |



|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001                |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>                  |  | Subject ID: MJ ____ ____ ____ ____          |                                     |
| Ongoing collected data through-out the study |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

| Study Day<br>(Study Part 1) | Date                                   | # Tobacco cigarettes smoked |
|-----------------------------|--|-----------------------------|
| 1                           | ____ / ____ / ____<br>mm    dd    yyyy |                             |
| 2                           | ____ / ____ / ____<br>mm    dd    yyyy |                             |
| 3                           | ____ / ____ / ____<br>mm    dd    yyyy |                             |
| 4                           | ____ / ____ / ____<br>mm    dd    yyyy |                             |
| 5                           | ____ / ____ / ____<br>mm    dd    yyyy |                             |

**Tobacco smoking is not permitted 1-hour prior to session initiation until 90 minutes after the completion of smoking the last marijuana cigarette of the day.**

|                              |  |
|------------------------------|--|
| Completed by: ____ ____ ____ | Date: ____ ____ / ____ ____ / <u>2 0 0</u> ____<br>m    m    d    d    y y y y |
|------------------------------|--|

|  |  |  |  |
|--|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>   |  | <b>Marinol – Marijuana Interaction Study</b>   |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>   |  | <b>Subject ID: MJ</b> _____ <b>Study Day #: _____</b>  |  |
| <b>Date:</b> _____ / _____ / <b><u>2 0 0</u></b><br><small>m m d d y y y y</small> |  | <b>Completed as required</b> <input type="radio"/> <span style="margin-left: 100px;"><b>Not completed</b> <input type="radio"/></span> |  |

Record height and weight and indicate appropriate units. Perform physical examination for each body system and record evaluation results below. Record comments for any body system with an abnormal evaluation result.

|   |  |   |  |
|---|--|---|--|
| <b>Height:</b> <input style="width: 80%;" type="text"/> | <input checked="" type="radio"/> <u>inches</u> | <b>Weight:</b> <input style="width: 80%;" type="text"/> | <input checked="" type="radio"/> <u>pounds</u> |
|---|--|---|--|

| Body System  | Evaluation            |                       |                       |                       | Provide comments for abnormal results |
|--|-----------------------|-----------------------|-----------------------|-----------------------|---------------------------------------|
|  | Normal                |                       | Abnormal              | Not Done              |                                       |
| Oral (mouth)   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Head and Neck  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| EENT   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Cardiovascular   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Lungs  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Abdomen<br>(include liver/spleen)                            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Extremities  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Skin   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Hair   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Nails  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Neuropsychiatric<br>mental status                            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Neuropsychiatric<br>sensory/motor                            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Musculoskeletal  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| General Appearance   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Other (specify)<br><input style="width: 100%;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |
| Other (specify)<br><input style="width: 100%;" type="text"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |                                       |

**Investigator's or designee's signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

|   |  |  |
|---|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                  | <b>Subject ID: MJ _____</b>                        |  |
| <b>Ongoing collected data through-out the study</b> | <b>Completed as required <input type="radio"/></b> | <b>Not completed <input type="radio"/></b> |

**Has the participant taken any prior medication 28 days before starting study participation?**

- Yes**
- No**

List all medications taken by the participant 28 days prior to the study. Indicate the name and reason the medication was taken. Include quantity, dosage, frequency and route of administration data for each medication.

Please list the date the participant started the medication and the date the medication was discontinued.

|  |  |  |  |  |  |                   |           |
|--|--|--|--|--|--|-------------------|-----------|
|  |  |  |  |  |  |                   |           |
|  |  |  |  |  |  | Start ___/___/___ | [PM STRT] |
|  |  |  |  |  |  | Stop ___/___/___  | [PM STOP] |
|  |  |  |  |  |  | Start ___/___/___ |           |
|  |  |  |  |  |  | Stop ___/___/___  |           |
|  |  |  |  |  |  | Start ___/___/___ |           |
|  |  |  |  |  |  | Stop ___/___/___  |           |
|  |  |  |  |  |  | Start ___/___/___ |           |
|  |  |  |  |  |  | Stop ___/___/___  |           |

**Use the suggested abbreviation codes below to complete the dosage, frequency and route fields:**

|  |  |  |   |   |  |  |  |
|--|--|--|---|---|--|--|--|
| <b>Dosage</b>  | <b>Dosage</b>  | <b>Dosage</b>  | <b>Dosage</b>   | <b>Frequency</b>  | <b>Route</b>   | <b>Route</b>   | <b>Route</b>   |
| CAP = capsule<br>g = gram<br>GR = grain<br>GTT = drop<br>GUM = Gum<br>LOP= Lollipop<br>LOT = Lotion/<br>ointment | ug = microgram<br>uL = microliter<br>mg = milligram<br>mL = milliliter<br>LOZ = Lozenge<br>Oz = ounce<br>PCH = Patch<br>PUF = puff | SPY = spray/squirt<br>SUP = suppository<br>TSP = teaspoon<br>TBS = tablespoon<br>IU = international<br>units | TAB = tablet<br>UNK = unknown<br>WFR = Wafer<br>OTH = other | ONCE = one dose<br>QD = once/day<br>BID = twice/day<br>TID = 3 times/day<br>QID = 4 times/day<br>QOD = every other day<br>PRN = as needed<br>UNK = unknown<br>OTH = other | PO = oral<br>TD = transdermal<br>INH = inhaled<br>IM = intramuscular<br>IV = intravenous | REC = rectal<br>VAG = vaginal<br>SL = sublingual<br>SQ = subcutaneous<br>AUR = auricular<br>IA = intra - articular | BUC = Buccal<br>NAS = nasal<br>IO = intraocular<br>OPT = Ophthalmic<br>TOP = Topical<br>UNK = unknown<br>OTH = other |

**Investigator's or designee's signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_



|   |  |  |                                     |
|---|--|--|-------------------------------------|
| NIDA-CPU- MARINOL - MJ -0001  |  | Marinol – Marijuana Interaction Study                          |                                     |
| Site ID: <u>9 9 0 1 0 1</u>   |  | Subject ID: MJ <u>    </u> <u>    </u> <u>    </u> <u>    </u> | Study Day #: <u>    </u>            |
| Date: <u>    </u> <u>    </u> / <u>    </u> <u>    </u> / <u>2 0 0</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/>                    | Not completed <input type="radio"/> |

Does subject have a diagnosis of any Axis I mental disorders based on DSM-IV criteria?

Yes

No

If Yes, then below provide name and code of disorder(s):

| Name of Past Disorder | DSM-IV | Name of Current Disorder | DSM-IV |
|-----------------------|--------|--------------------------|--------|
| 1.                    |        | 1.                       |        |
| 2.                    |        | 2.                       |        |
| 3.                    |        | 3.                       |        |
| 4.                    |        | 4.                       |        |
| 5.                    |        | 5.                       |        |
| 6.                    |        | 6.                       |        |
| 7.                    |        | 7.                       |        |
| 8.                    |        | 8.                       |        |
| 9.                    |        | 9.                       |        |

|   |   |
|---|---|
| Completed by: <u>    </u> <u>    </u> <u>    </u> | Date: <u>    </u> <u>    </u> / <u>    </u> <u>    </u> / <u>2 0 0</u><br>m m    d d    y y y y |
|---|---|

|   |  |
|---|--|
| <b>NIDA-CPU-MARINOL – MJ - 0001</b>                 | <b>Marinol – Marijuana Interaction Study</b>   |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                  | <b>Subject ID: MJ _____</b>  |
| <b>Ongoing collected data through-out the study</b> | <b>Completed as required <input type="radio"/> Not completed <input type="radio"/></b> |

|  |   |  |                                  |   |   |
|--|---|--|----------------------------------|---|---|
| <b>Gender</b>  | <input type="radio"/> Male<br><input type="radio"/> Female  | <b>Date of Birth</b>   | ____ / ____ / _____ (mm/dd/yyyy) |   |   |
| <b>Height</b>  | <input style="width: 100px; height: 20px;" type="text"/>  | <input type="radio"/> inches   | <input type="radio"/> pounds     |   |   |
| <b>SAE Report Type</b>   | <input type="radio"/> Initial <input type="radio"/> Follow-up   |  |                                  |   |   |
| <b>SAE Name (name of event)</b>  |   |  |                                  |   |   |
| <b>SAE Onset</b>   | ____ / ____ / _____ (mm/dd/yyyy)  | <b>SAE Resolution</b>  | ____ / ____ / _____ (mm/dd/yyyy) |   |   |
| <b>SAE Categorization - indicate Yes for all that apply</b>                                  |   |  |                                  |   |   |
| Yes  |   |  | Yes                              |   |   |
| <input type="radio"/>  | <input type="radio"/>   | Death  | <input type="radio"/>            | <input type="radio"/>   | Congenital Anomaly, (indicate anomaly classification)<br>Specify: |
| <input type="radio"/>  | <input type="radio"/>   | Life Threatening   | <input type="radio"/>            | <input type="radio"/>   | Pregnancy   |
| <input type="radio"/>  | <input type="radio"/>   | Hospitalization (initial or prolonged)   | <input type="radio"/>            | <input type="radio"/>   | Required Intervention to Prevent Permanent Impairment/Damage      |
| <input type="radio"/>  | <input type="radio"/>   | Disability, Specify:   | <input type="radio"/>            | <input type="radio"/>   | Other, Specify:   |
| <b>SAE</b>   | <input type="radio"/> Unexpected <input type="radio"/> Expected   |  |                                  |   |   |
| <b>Severity of SAE</b>   | <b>Relationship to</b>  | <b>SAE Actions Taken</b>   |                                  | <b>SAE Outcome</b>  |   |
| <input type="radio"/> Mild<br><input type="radio"/> Moderate<br><input type="radio"/> Severe | <input type="radio"/> Definitely<br><input type="radio"/> Probably<br><input type="radio"/> Possibly<br><input type="radio"/> Remotely<br><input type="radio"/> Definitely Not<br><input type="radio"/> Unknown | <input type="radio"/> No Action<br><input type="radio"/> Study agent discontinued permanently<br><input type="radio"/> Study agent discontinued temporarily<br><input type="radio"/> Reduced dose study agent<br><input type="radio"/> Increased dose study agent<br><input type="radio"/> Delayed dose study agent<br><input type="radio"/> Continued Dose<br><input type="radio"/> Unknown |                                  | <input type="radio"/> Recovered/resolved<br><input type="radio"/> Recovering/resolving<br><input type="radio"/> Not recovered/not resolved<br><input type="radio"/> Recovered/resolved with sequelae<br><input type="radio"/> Lost to Follow Up<br><input type="radio"/> Fatal<br><br><b>Date of Death</b><br>____ / ____ / ____<br>m m / d d / y y y y |   |





|  |  |  |
|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                                   | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                                     | <b>Subject ID: MJ</b> _____                        | <b>Study Day #: _____</b>                  |
| <b>Date:</b> _____ / _____ / <b>200</b><br>m m       d d       y y y y | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Smoking Session Start Time | Smoking Session Stop Time | Session Administered By |
|----------------------------|---------------------------|-------------------------|
| (24-hour clock) _____      | (24-hour clock) _____     | _____                   |

| Time per<br>l | Actual Time   | Assessments Performed   | Initials |  |
|---------------|---------------|---|----------|--|
| <b>0900</b>   | _____ . _____ | <b>Smoke placebo cigarette</b><br>Light up – 30 sec<br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec   | _____    |  |
|               | _____ . _____ | <b>Smoke placebo cigarette</b><br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec                        | _____    |  |
|               | _____ . _____ | <b>Smoke placebo cigarette</b><br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec                        | _____    |  |
| <b>1000</b>   | _____ . _____ | <b>Smoke marijuana cigarette</b><br>Light up – 30 sec<br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec | _____    |  |
|               | _____ . _____ | <b>Smoke marijuana cigarette</b><br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec                      | _____    |  |
|               | _____ . _____ | <b>Smoke marijuana cigarette</b><br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec                      | _____    |  |

|   |  |  |  |
|---|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>  |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date: <u>    </u> / <u>    </u> / <u>2 0 0</u></b><br><small>m m d d y y y y</small> |  | <b>Completed as required <input type="radio"/></b> | <b>Not completed <input type="radio"/></b> |

| Time per<br>l | Actual Time   | Assessments Performed   | Initials |  |
|---------------|---------------|---|----------|--|
| 1100          | _____ . _____ | <b>Smoke marijuana cigarette</b><br>Light up – 30 sec<br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec | _____    |  |
|               | _____ . _____ | <b>Smoke marijuana cigarette</b><br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec                      | _____    |  |
|               | _____ . _____ | <b>Smoke marijuana cigarette</b><br>Get ready – 5 sec<br>Inhale – 5 sec<br>Hold – 10 sec<br>Exhale and wait – 35 sec                      | _____    |  |

Completed by: \_\_\_\_\_

Date:      /      / 2 0 0  
m m d d y y y y

|  |  |  |  |
|--|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                 |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                   |  | <b>Subject ID: MJ _____</b>                        |  |
| <b>Ongoing collected data through- out the study</b> |  | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

Compliance with investigational agents will be recorded every time a capsule is dispensed to a subject, or a marijuana or placebo cigarette is smoked by a subject.

| Study    | Time (24-hour clock) |       | *Reason Not Done |  | Notes/Comments |
|----------|----------------------|-------|------------------|--|----------------|
|          |                      |       |                  |  |                |
| <b>1</b> |                      |       |                  |  |                |
| <b>2</b> | 0900 cigarette       | _____ |                  |  |                |
|          | 1000 cigarette       | _____ |                  |  |                |
|          | 1100 cigarette       | _____ |                  |  |                |
| <b>3</b> | 0900 cigarette       | _____ |                  |  |                |
|          | 1000 cigarette       | _____ |                  |  |                |
|          | 1100 cigarette       | _____ |                  |  |                |
| <b>4</b> | 0800 capsule         | _____ |                  |  |                |
|          | 1100 capsule         | _____ |                  |  |                |
|          | 1400 capsule         | _____ |                  |  |                |
|          | 1700 capsule         | _____ |                  |  |                |
|          | 2000 capsule         | _____ |                  |  |                |
| <b>5</b> | 0800 capsule         | _____ |                  |  |                |
|          | 1100 capsule         | _____ |                  |  |                |
|          | 1400 capsule         | _____ |                  |  |                |
|          | 1700 capsule         | _____ |                  |  |                |
|          | 2000 capsule         | _____ |                  |  |                |
| <b>6</b> | 0800 capsule         | _____ |                  |  |                |
|          | 1100 capsule         | _____ |                  |  |                |
|          | 1400 capsule         | _____ |                  |  |                |
|          | 1700 capsule         | _____ |                  |  |                |
|          | 2000 capsule         | _____ |                  |  |                |

|  |  |  |
|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                 | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                   | <b>Subject ID: MJ</b> _____                        |  |
| <b>Ongoing collected data through- out the study</b> | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Study     | Time (24 hour clock) | *Reason Not Done | Notes/Comments |
|-----------|----------------------|------------------|----------------|
| <b>7</b>  | 0800 capsule         | _____            |                |
|           | 1100 capsule         | _____            |                |
|           | 1400 capsule         | _____            |                |
|           | 1700 capsule         | _____            |                |
|           | 2000 capsule         | _____            |                |
| <b>8</b>  | 0800 capsule         | _____            |                |
|           | 1100 capsule         | _____            |                |
|           | 1400 capsule         | _____            |                |
|           | 1700 capsule         | _____            |                |
|           | 2000 capsule         | _____            |                |
| <b>9</b>  | 0800 capsule         | _____            |                |
|           | 0900 cigarette       | _____            |                |
|           | 1000 cigarette       | _____            |                |
|           | 1100 cigarette       | _____            |                |
|           | 1700 capsule         | _____            |                |
|           | 2000 capsule         | _____            |                |
| <b>10</b> | 0800 capsule         | _____            |                |
|           | 0900 cigarette       | _____            |                |
|           | 1000 cigarette       | _____            |                |
|           | 1100 cigarette       | _____            |                |

**\*Reason Not Done- Codes**

|   |   |
|---|---|
| <p><b>1. Participant’s refusal</b></p> <p><b>2. Participant withdrew from study</b></p> | <p><b>3. Participant was terminated from study</b></p> <p><b>4. Other</b></p> |
| Completed by: _____   | Date: _____ / _____ / <u>200</u><br><small>m m d d y y y y</small>            |

|   |  |  |
|---|--|--|
| <b>NIDA-CPU- MARINOL - MJ 0001</b>  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  | <b>Subject ID: MJ _____</b>                        | <b>Study Day #: _____</b>                  |
| <b>Date: _____ / _____ / <u>2 0 0</u></b><br><small>m m d d y y y y</small> | <b>Completed as required</b> <input type="radio"/> | <b>Not Completed</b> <input type="radio"/> |

|   |   |
|---|---|
| <b>Specific gravity =</b> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> | <b>Urine pH =</b> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> |
|---|---|

Complete the result level for each urinalysis parameter below. Indicate whether each urinalysis parameter measurement is Normal (within laboratory normal limits), Abnormal (outside of laboratory normal limits but not clinically significant), Abnormal Significant (outside laboratory normal limits and clinically significant), or Not Done. Provide comments for any abnormal or significantly abnormal values below.

| Urinalysis | 0                     | Trace                 | +1                    |                       |                       |                       | Quantity | Unit |                       |                       | Abnormal              | Not                   |
|------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|------|-----------------------|-----------------------|-----------------------|-----------------------|
|            | <input type="radio"/> |          |      |                       |                       |                       |                       |
| Blood      | <input type="radio"/> |          |      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Protein    | <input type="radio"/> |          |      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Glucose    | <input type="radio"/> |          |      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Ketones    | <input type="radio"/> |          |      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Leukocytes | <input type="radio"/> |          |      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Nitrites   | <input type="radio"/> |          |      | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

**\*Provide comments for any abnormal or significantly abnormal results:**

|                     |  |
|---------------------|--|
| Completed by: _____ | Date: _____ / _____ / <u>2 0 0</u><br><small>m m d d y y y y</small> |
|---------------------|--|

|                                |  |   |                                     |
|--------------------------------|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001  |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>990101</u>         |  | Subject ID: MJ ___ ___ ___                  |                                     |
| Collected data within 24 hours |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

| Date of Urine | Study | Time of Urine Specimen Collection  | Volume of Urine |
|---------------|-------|--|-----------------|
| ___/___/____  | ____  | Start collecting a voided urine specimen after the first cigarette was smoked<br><br>_____         |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | _____  |                 |
| ___/___/____  | ____  | Last voided urine specimen collected at 24 hours after the first cigarette was smoked<br><br>_____ |                 |

Urine samples for Δ-9-THCV testing will be collected as separate volumes as they are voided with the last specimen collected at approximately 24 hours after the first cigarette was smoked (record the volume, take a 20 mL aliquot and then discard the sample)

A 20 mL aliquot of each urine sample will be frozen and analyzed for Δ-9-THCV-COOH content by gas chromatograph-mass spectroscopy (GC-MS)

|                           |   |
|---------------------------|---|
| Completed by: ___ ___ ___ | Date: ___/___/200___<br>m m d d y y y y |
|---------------------------|---|

|   |  |   |                                     |
|---|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001                     |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>990101</u>                            |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date: ____ / ____ / <u>200</u><br>m m d d y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

This form captures the results from urine drug screens performed with an FDA approved on-site urine testing kit

**1. Was a Urine Drug Screen Performed?**

Yes  \*No  \*Not Done  \*Unknown

\*If one of the above, do not fill in data for items 2 – 5

**2. Date urine collected (mm/dd/yyyy):** \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

**3. Urine temperature within expected range?**

Yes  No

**4. Was this urine collection supervised?**

Yes  No

**5. Urine Drug Screen Results (below):**

(Fill in the bubble in the column representing the drug screen result for each substance listed below)

**Result Values**

| Drug Name / Classification       | Negative              | Positive              | Not Done              | Unknown               |
|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 1. Cocaine metabolites (COC)     | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. Cannabinoids (THC)            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. Amphetamines (AMP)            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. Opiates/Morphine/Heroin (MOR) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. Benzodiazepines (BZP)         | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

|                    |   |
|--------------------|---|
| Completed by: ____ | Date: ____ / ____ / <u>200</u><br>m m d d y y y y |
|--------------------|---|

|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ 0001                          |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>990101</u>                               |  | Subject ID: MJ _____ Study Day #: _____     |                                     |
| Date : _____ / _____ / <u>200</u><br>m m d d y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

**Pregnancy Test**

**Not applicable** (male subject)

|   |   |
|---|---|
| 1. Was a pregnancy test performed?  | <input type="radio"/> Yes <input type="radio"/> No            |
| 2. Pregnancy test result:   | <input type="radio"/> Positive <input type="radio"/> Negative |
| 3. Is the subject using an acceptable method of birth control?  | <input type="radio"/> Yes <input type="radio"/> No            |
| 4. What method of birth control is the subject using?   |   |
| <input type="radio"/> Subject is postmenopausal<br><input type="radio"/> Subject had a hysterectomy<br><input type="radio"/> Subject is sterile<br><input type="radio"/> Complete abstinence from sexual intercourse<br><input type="radio"/> Diaphragm, and condom by partner<br><input type="radio"/> Sponge, and condom by partner<br><input type="radio"/> Intrauterine device/progesterone or non-hormonal contraceptive system<br><input type="radio"/> Hormonal contraceptives: oral/patch/implant/injection |   |
| 5. Pregnancy test comments:   |   |
|   |   |

|                     |   |
|---------------------|---|
| Completed by: _____ | Date: _____ / _____ / <u>200</u><br>m m d d y y y y |
|---------------------|---|

|   |  |  |  |
|---|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                          |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>                            |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date : _____ / _____ / <u>2 0 0</u></b><br>m m d d y y y y |  | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

The VAS assessments are performed after the MWSC daily, except on smoking sessions days when they are taken prior to and approximately 7, 10, 20, 30 and 50 minutes after each of the 3 cigarettes.

| <b>After MWSC</b> <input type="radio"/>                   |             |  |  |
|---|-------------|--|--|
| Time Interval   | Actual Time | VAS Questions                                  |  |
| <b>After 1430<br/>(After MWSC)</b>                        | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>Smoking Session</b> <input type="radio"/>              |             |  |  |
| <b>0845-0859<br/>Baseline<br/>(-15 min to -1 min)</b>     | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>0907<br/>7 minutes<br/>After smoking cigarette #1</b>  | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>0910<br/>10 minutes<br/>After smoking cigarette #1</b> | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>0920<br/>20 minutes<br/>After smoking cigarette #1</b> | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>0930<br/>30 minutes<br/>After smoking cigarette #1</b> | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>0950<br/>50 minutes<br/>After smoking cigarette #1</b> | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |

|   |  |  |  |
|---|--|--|--|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                                      |  | <b>Marinol – Marijuana Interaction Study</b>       |  |
| <b>Site ID: <u>9 9 0 1 0 1</u></b>  |  | <b>Subject ID: MJ _____ Study Day #: _____</b>     |  |
| <b>Date : _____ / _____ / <u>2 0 0</u></b><br>m    m    d    d    y y y y |  | <b>Completed as required</b> <input type="radio"/> | <b>Not completed</b> <input type="radio"/> |

| Time Interval   | Actual Time | VAS Questions                                  |  |
|---|-------------|--|--|
| <b>1007</b><br>7 minutes<br>After smoking cigarette #2  | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1010</b><br>10 minutes<br>After smoking cigarette #2 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1020</b><br>20 minutes<br>After smoking cigarette #2 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1030</b><br>30 minutes<br>After smoking cigarette #2 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1050</b><br>50 minutes<br>After smoking cigarette #2 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1107</b><br>7 minutes<br>After smoking cigarette #3  | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1110</b><br>10 minutes<br>After smoking cigarette #3 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1120</b><br>20 minutes<br>After smoking cigarette #3 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1130</b><br>30 minutes<br>After smoking cigarette #3 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |
| <b>1150</b><br>50 minutes<br>After smoking cigarette #3 | _____       | 1. How high do you feel now?                   |  |
|   |             | 2. How stoned on MJ are you now?               |  |
|   |             | 3. How strong is the drug effect you feel now? |  |

|  |  |   |                                     |
|--|--|---|-------------------------------------|
| NIDA-CPU- MARINOL - MJ - 0001  |  | Marinol – Marijuana Interaction Study       |                                     |
| Site ID: <u>9 9 0 1 0 1</u>  |  | Subject ID: MJ ____ Study Day #: ____       |                                     |
| Date : <u>    </u> / <u>    </u> / <u>2 0 0</u><br>m m    d d    y y y y |  | Completed as required <input type="radio"/> | Not completed <input type="radio"/> |

| *VAS Question                                  |  |
|--|--|
| 1. How high do you feel now?                   |  |
| 2. How stoned on MJ are you now?               |  |
| 3. How strong is the drug effect you feel now? |  |

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|--------------------|---|
| Completed by: ____ | Date: <u>    </u> / <u>    </u> / <u>2 0 0</u><br>m m    d d    y y y y |
|--------------------|---|

|   |   |
|---|---|
| <b>NIDA-CPU- MARINOL - MJ - 0001</b>                                  | <b>Marinol – Marijuana Interaction Study</b>                                    |
| Site ID: <u>9 9 0 1 0 1</u>   | Subject ID: MJ _____ Study Day #: _____   |
| Date : _____ / _____ / <u>2 0 0</u><br><small>m m d d y y y y</small> | Completed as required <input type="radio"/> Not completed <input type="radio"/> |

Daily routine vital signs to be assessed include oral temperature, sitting blood pressure, pulse rate and respiratory rate:

| _____ |  | <input type="radio"/> °F |  |  |  |  |
|-------|--|--------------------------|--|--|--|--|
| _____ |  | <input type="radio"/> °F |  |  |  |  |
| _____ |  | <input type="radio"/> °F |  |  |  |  |
| _____ |  | <input type="radio"/> °F |  |  |  |  |
| _____ |  | <input type="radio"/> °F |  |  |  |  |

|                  |
|------------------|
| <b>Comments:</b> |
|                  |
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|                  |

|                     |  |
|---------------------|--|
| Completed by: _____ | Date: _____ / _____ / <u>2 0 0</u><br><small>m m d d y y y y</small> |
|---------------------|--|