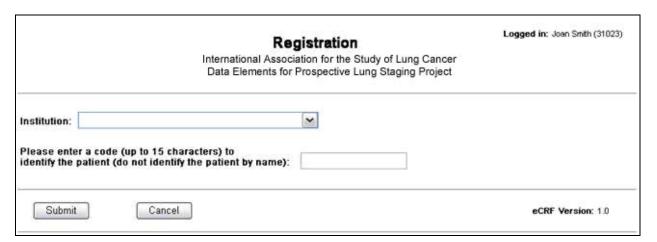
# The International Association for the Study of Lung Cancer (IASLC) Prospective Lung Cancer Staging Project

# APPENDIX TO PROCOTOL FOR PURPOSE OF GRANT APPLICATION AND ETHICS REVIEW

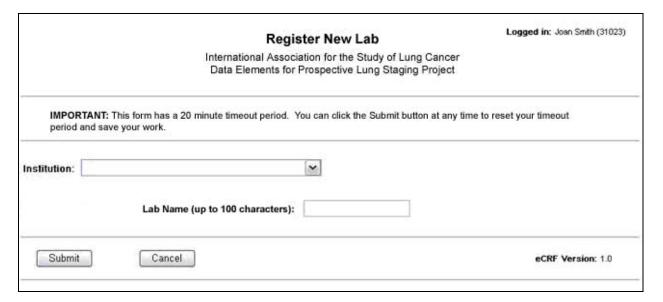
#### **TABLE OF CONTENTS**

| 18.1 Registration   | A2    |
|---|-------|
| 18.2 Register New Lab   | A2    |
| 18.3 Patient Characteristics  | A3    |
| 18.4 Pre-Treatment/Evaluative Laboratory Values                                 | A5    |
| 18.5 Disease Description at Diagnosis   | A7    |
| 18.6 Basis for Pre-Treatment/Evaluation Findings                                | A9    |
| 18.7 Treatments   | . A11 |
| 18.8 T-Descriptors, by Pre-Treatment/Evaluation Findings                        | . A13 |
| 18.9 Pre-treatment/Evaluative N Category Based on Clinical/Imaging Assessment   | . A16 |
| 18.10 Pre-treatment/Evaluative N Category Based on Cytology or Biopsy Results   | . A18 |
| 18.11 Additional Nodules, by Pre-Treatment/Evaluative Findings                  | . A20 |
| 18.12 T-Descriptors by Post-Surgical/Pathological Findings                      | . A22 |
| 18.13 Post-Surgical/Pathological N Category                                     | . A25 |
| 18.14 Additional Nodules, by Post-Surgical/Pathological Findings                | . A27 |
| 18.15 M-Descriptors, No Attempt to Resect Primary Tumour                        | . A29 |
| 18.16 M-Descriptors, Before and After Attempted Resection of the Primary Tumour | A31   |

#### 18.1 Registration



### 18.2 Register New Lab



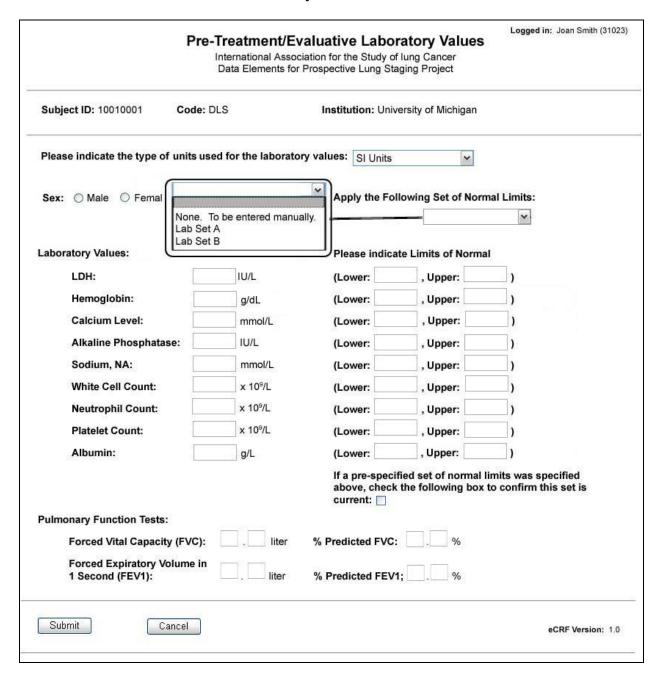
## **18.3 Patient Characteristics**

| Patient Characteristics International Association for the Study of Lung Cancer |  |                                |   | Logged in: Joan Smith (31023)   |  |  |  |
|--|--|--------------------------------|---|---------------------------------|--|--|--|
| Data Elements for Prospective Lung Staging Project                             |  |                                |   |                                 |  |  |  |
| Subject ID: 10010001   | Code: DLS                                    | Ins                            | titution: University of Michi                     | igan                            |  |  |  |
| IMPORTANT: This form ha<br>period and save your work.                          |  | eriod. You can                 | click the Submit button at a                      | ny time to reset your timeout   |  |  |  |
| Patient birth date: Day  | Month Year (yyyy)                            |                                |   |                                 |  |  |  |
| Sex: O Male O Female   | •  |                                |   |                                 |  |  |  |
| ~  | an<br>ite or Caucasian<br>er/Mixed/Uncertain |                                | or African American<br>an Indian/Alaskan Native/P | acific Islander                 |  |  |  |
| Smoking history (select o  | One): O Never smoked                         |                                |   |                                 |  |  |  |
| If a former smoker, numb   | er of years since quitt                      | ing?                           |   |                                 |  |  |  |
| Number of years smoked   | :  |                                |   |                                 |  |  |  |
| Weight loss in previous s  | six months (select one                       | ): () > 5%                     | O = 5%</td <td></td>                              |                                 |  |  |  |
| Zubrod Performance Stat  |  | ally active<br>mited self care | Restricted     Completely diabled                 | No work, ambulatory     Unknown |  |  |  |
| Height: cm   | Weight:                                      | . kg                           |   |                                 |  |  |  |
|  |  |                                |   |                                 |  |  |  |
|  |  |                                |   |                                 |  |  |  |

## **18.3 Patient Characteristics (Continued)**

|  |   |   |  |  | This field is automatically filled based on the answer given for  |
|--|---|---|--|--|---|
| Tobacco consumption  | Yes   |   |  |  | the Smoking History field.  |
| Diabetes mellitus  | 0   | Yes   | O No   | O No data  |   |
| Renal insufficiency  | 0   | Yes   | O No   | O No data  |   |
| Respiratory comorbidity  | 0   | Yes   | O No   | O No data  |   |
| Cardiovascular comorbidity   | 0   | Yes   | O No   | O No data  |   |
| Previously treated malignancy (other than squamous skin cancer)  | 0   | Yes   | ○ No   | O No data  |   |
| Alcoholism   | 0   | Yes   | O No   | O No data  |   |
| THE PARTY SERVICE AND ADDRESS AND  | 25  |   |  |  |   |
| This box is to be checked only fo<br>be separate "primary" tumours a<br>document treatment and staging<br>primary tumour as #1 and the oth<br>for primary tumour #1 (identified  | r tho<br>s def<br>data<br>ner as  | se cas<br>fined b<br>separ<br>s #2. A   | ses in which<br>elow. If a<br>rately for ea  | h the synchrono<br>patient has mult<br>ach primary tum<br>nt and staging fo  | ous and multiple tumours are considered to iple synchronous tumours, please our. Please consistently designate one orms will need to be completed twice, once ary tumour #2 (identified by TUMOUR2  |
| be separate "primary" tumours as document treatment and staging primary tumour as #1 and the oth for primary tumour #1 (identified tab).  The classification of additional tumo a) In most situations in which additional tumours, with identical histological a such tumours are classified as T3, vcontralateral lung are designated M b) Multiple tumours may be conside tumours of simialr histological apper of the pathologist, based on feature immunohistochemistry and/or molecular and the staging and the pathologist, based on feature immunohistochemistry and/or molecular and staging a | or thoose default of the control of | ose cas<br>fined b<br>separ<br>s #2. A<br>UMOU<br>odules<br>tumour<br>arance:<br>a found<br>to be sy<br>ce shoo | ses in whice selow. If a partely for eat all treatment R1 tab) and in lung can reduce a so to that of in other ips yetheronous uld only be associated cos, they repr | the synchronor patient has multi- ach primary turn than staging for again for primare depends upon the found in associate primary turnouilateral lobes are primaries if they considered to be arcinoma in situ desent differeing s | iple synchronous tumours, please our. Please consistently designate one orms will need to be completed twice, once ary tumour #2 (identified by TUMOUR2  In their histological appearances. ation with a lung primary these are metastatic ur. If limited to the lobe of the primary tumour designated as T4 and if found in the are of different histological cell types. Multiple synchronous primary tumours if in the opinion |

#### 18.4 Pre-Treatment/Evaluative Laboratory Values



The appearance of the form will change depending how the "Please indicate the type of units used for the laboratory values" question is answered. When "Conventional Units" is selected, the form will use Conventional units for each of the laboratory values.

## **18.4 Pre-Treatment/Evaluative Laboratory Values (Continued)**

|  | Logged in: Joan Smith (31023)                 |                         |                      |   |
|--|---|-------------------------|----------------------|---|
| Subject ID: 10010001                     | Code: DLS                                     | Institution: Un         | iversity of Michigan |   |
| Please indicate the type o               | f units used for the lat                      | poratory values: Conven | tional Units         |   |
| Sex: O Male O Femal                      |   |                         | ollowing Set of Norr | -   |
|  | None. To be entered<br>Lab Set A<br>Lab Set B |                         |                      |   |
| Laboratory Values:                       |   |                         | ate Limits of Norma  | 10  |
| LDH:                                     | IU/L  | (Lower:                 | , Upper:             | )   |
| Hemoglobin:                              | g/dl  | (Lower:                 | , Upper:             | )   |
| Calcium Level:                           | mg/dl   | (Lower:                 | , Upper:             | )   |
| Alkaline Phosphata                       | se: IU/L                                      | (Lower:                 | , Upper:             | )   |
| Sodium, NA:                              | mEq/L   | (Lower:                 | , Upper:             | )   |
| White Cell Count:                        | x 10 <sup>3</sup> /m                          | m³ (Lower:              | , Upper:             | )   |
| Neutrophil Count:                        | x 10 <sup>3</sup> /m                          | m³ (Lower:              | , Upper:             | )   |
| Platelet Count:                          | x 10 <sup>3</sup> /m                          | m³ (Lower:              | , Upper:             | )   |
| Albumin:                                 | g/dl  | (Lower:                 | , Upper:             | )   |
|  |   |                         |                      | limits was specified to confirm this set is |
| Pulmonary Function Tests:                |   |                         |                      |   |
| Forced Vital Capacity                    | (FVC): li                                     | ter % Predicted FVC     | : . %                |   |
| Forced Expiratory Vo<br>1 Second (FEV1): |   | ter % Predicted FEV     | 1; %                 |   |
| Submit Ca                                |   |                         |                      |   |

## **18.5 Disease Description at Diagnosis**

|  |                                  | International A                    | Description at D<br>ssociation for the Study<br>ts for Prospective Lung  | of Lung Cancer   |
|--|----------------------------------|------------------------------------|--|--|
| Subject ID: 10010001<br>Tumour: #1             | Code:                            | DLS                                | Institution: Univ  | versity of Michigan  |
| MPORTANT: This form<br>period and save your wo |                                  | ute timeout period                 | f. You can click the Sub   | mit button at any time to reset your timeout                   |
| Method of detection (s                         | elect one):                      | O Symptoms                         | O Incidental   |  |
|  |                                  | Screening                          | <ul><li>No data</li></ul>  |  |
| Diagnosed by:                                  |                                  |                                    |  |  |
|  | O Yes                            |                                    |  |  |
| Cytology:                                      | 10000                            | If ves. da                         | te cytology obtained:  | - 💌 -  |
| -,5,-  | O No data                        | 1884 <b>4</b> 65 5 <b>1</b> 65 5 5 |  | Day Month Year (yyyy)  |
|  | 19112 MGH2                       |                                    |  |  |
| Histology:                                     | O Yes                            | If you dat                         | te histology obtained:   | - W-   |
| Histology.                                     | O No data                        | ii yes, uai                        | te ilistology obtailled.   | Day Month Year (yyyy)  |
| nodules (select all tha                        |                                  | 2 15                               | ta on location   | ations of the involved nodes or additional                     |
| Mark Control Control                           |                                  |                                    |  | and the second second second                                   |
| Right Main Bro                                 |                                  |                                    | Bronchus, Side Not Spe   |  |
| Right Upper Lo                                 |                                  | ☐ Trach                            |  | Left Upper Lobe  |
| Right Middle Lo                                |                                  | Carina                             | 3  | ☐ Left Lower Lobe ☐ Left Upper Lobar Bronchus                  |
| Right Lower Lo                                 |                                  |                                    |  | ☐ Left Lower Lobar Bronchus                                    |
| Right Upper Lo                                 |                                  |                                    |  | Ent Lower Lobal Biolicitus                                     |
| ☐ Right Middle Lo                              |                                  | 5                                  |  |  |
| Right Lower Lo                                 |                                  |                                    |  |  |
|  |                                  |                                    | from tour date on the  |  |
|  |                                  |                                    | from input above):   |  |
| Differentiation grade (                        | select one):                     |                                    |  | G3: Porrly differentiated                                      |
|  |                                  | G1: well diffe                     |  | No data  |
|  |                                  | G2: moderate                       | ely differentiated   |  |
| Histologic Type (WHO                           | Classificati                     | on, 2004 Edition)                  | :  | Label, automatically calculat<br>from input given for previous |
|  |                                  |                                    |  | questions.   |
|  |                                  |                                    |  |  |
|  |                                  |                                    |  | <u> </u>   |
| Small cell ca                                  | rcinoma (or c                    | ombined SCLC)                      |  |  |
| Adenocarcine<br>Adeno-squar                    |                                  |                                    |  |  |
| Squamous                                       |                                  |                                    |  |  |
|  | oma, bronchie<br>uroendocrine    | oloalveolar<br>(or combined LCI    | VEC)   |  |
| Large cell, no                                 | ot otherwise s                   | pecified                           | and the same of th |  |
| Non-small ce<br>Carcinoid - ty                 |                                  | ise specified (or lis              | sted above)  |  |
| Carcinoid - a                                  | typical                          |                                    |  |  |
|  | ot otherwise :<br>e tumourlet (< |                                    |  |  |
| Mixed non-sr                                   | mall cell                        |                                    |  |  |
| Sarcomatoid<br>Mixed other                     | carcinoma (i                     | ncluding pleomorp                  | hic carcinoma and carci  | nosarcoma)   |
| Other  |                                  |                                    |  |  |

## **18.5 Disease Description at Diagnosis (Continued)**

|         | gic type is official co | ell carcinoma (  | or combined S                | CLC),' plea  | se comple    | te the following:                                  |
|---------|-------------------------|------------------|------------------------------|--------------|--------------|--|
| E       | xtent of Disease: (     | ) Limited disea  | se C Exte                    | ensive disea | se O         | No data on extent                                  |
| P       | araneoplastic syndi     | ome: O Yes       | O No                         | O No data    | i            |  |
|         | If yes, please cor      | nplete the follo | wing:                        |              |              |  |
|         | SIADH:                  |                  |                              | O Yes        | O No         | O No data  |
|         | Ectopic A               | стн:             |                              | O Yes        | O No         | O No data  |
|         | Myasther                | ic Syndrome (    | LEMS, ELS):                  | O Yes        | O No         | O No data  |
| LCNEC), |                         | al,' 'Carcindoid | - atypical,' 'Ca             |              |              | uroendocrine (or comb<br>se specified,' or 'Carcin |
|         | Chromogranin:           | O Positive       | <ul> <li>Negative</li> </ul> | ○ Equ        | ivocal/No o  | lata   |
|         | Synaptophysin:          | O Positive       | <ul><li>Negative</li></ul>   | ○ Equ        | iivocal/No o | lata   |
|         | o)p.topyo               |                  |                              |              |              |  |