

**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

Registration		Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project		
<hr/>		
Institution:	<input type="text"/>	
Please enter a code (up to 15 characters) to identify the patient (do not identify the patient by name): <input type="text"/>		
<hr/>		
<input type="button" value="Submit"/>	<input type="button" value="Cancel"/>	eCRF Version: 1.0

18.2 Register New Lab

Register New Lab		Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project		
<hr/>		
IMPORTANT: This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.		
<hr/>		
Institution:	<input type="text"/>	
Lab Name (up to 100 characters): <input type="text"/>		
<hr/>		
<input type="button" value="Submit"/>	<input type="button" value="Cancel"/>	eCRF Version: 1.0

18.3 Patient Characteristics

Patient Characteristics			Logged in: Joan Smith (31023)
International Association for the Study of Lung Cancer Data Elements for Prospective Lung Staging Project			
Subject ID: 10010001	Code: DLS	Institution: University of Michigan	
IMPORTANT: This form has a 20 minute timeout period. You can click the Submit button at any time to reset your timeout period and save your work.			
Patient birth date:	<input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>	
	Day	Month	Year (yyyy)
Sex:	<input type="radio"/> Male <input type="radio"/> Female		
Race (select one):	<input type="radio"/> Asian <input type="radio"/> Black or African American <input type="radio"/> White or Caucasian <input type="radio"/> American Indian/Alaskan Native/Pacific Islander <input type="radio"/> Other/Mixed/Uncertain		
Smoking history (select one):	<input type="radio"/> Never smoked <input type="radio"/> Former smoker <input type="radio"/> Current smoker <input type="radio"/> No data		
If a former smoker, number of years since quitting?	<input type="text"/>		
Number of years smoked:	<input type="text"/>		
Weight loss in previous six months (select one):	<input type="radio"/> > 5% <input type="radio"/> </= 5%		
Zubrod Performance Status (select one):	<input type="radio"/> Fully active <input type="radio"/> Restricted <input type="radio"/> No work, ambulatory <input type="radio"/> Limited self care <input type="radio"/> Completely disabled <input type="radio"/> Unknown		
Height: <input type="text"/> cm	Weight: <input type="text"/> . <input type="text"/> kg		

18.3 Patient Characteristics (Continued)

Cormorbidity:

Tobacco consumption Yes This field is automatically filled based on the answer given for the Smoking History field.

Diabetes mellitus Yes No No data

Renal insufficiency Yes No No data

Respiratory comorbidity Yes No No data

Cardiovascular comorbidity Yes No No data

Previously treated malignancy (other than squamous skin cancer) Yes No No data

Alcoholism Yes No No data

Date of trial entry if patient was enrolled on a clinical trial: - -
Day Month Year (yyyy)

Check here if patient had multiple synchronous tumours

This box is to be checked only for those cases in which the synchronous and multiple tumours are considered to be separate "primary" tumours as defined below. If a patient has multiple synchronous tumours, please document treatment and staging data separately for each primary tumour. Please consistently designate one primary tumour as #1 and the other as #2. All treatment and staging forms will need to be completed twice, once for primary tumour #1 (identified by TUMOUR1 tab) and again for primary tumour #2 (identified by TUMOUR2 tab).

The classification of additional tumour nodules in lung cancer depends upon their histological appearances.

a) In most situations in which additional tumour nodules are found in association with a lung primary these are metastatic nodules, with identical histological appearances to that of the primary tumour. If limited to the lobe of the primary tumour such tumours are classified as T3, when found in other ipsilateral lobes are designated as T4 and if found in the contralateral lung are designated M1a.

b) Multiple tumours may be considered to be synchronous primaries if they are of different histological cell types. Multiple tumours of similar histological appearance should only be considered to be synchronous primary tumours if in the opinion of the pathologist, based on features such as associated carcinoma in situ or differences in morphology, immunohistochemistry and/or molecular studies, they represent differing sub-types of the same histopathological cell type, and also have no evidence of mediastinal nodal metastases or of nodal metastases within a common nodal drainage.

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18.4 Pre-Treatment/Evaluative Laboratory Values

Logged in: Joan Smith (31023)

Pre-Treatment/Evaluative Laboratory Values

International Association for the Study of Lung Cancer
Data Elements for Prospective Lung Staging Project

Subject ID: 10010001 **Code:** DLS **Institution:** University of Michigan

Please indicate the type of units used for the laboratory values:

Sex: Male Female

Apply the Following Set of Normal Limits:

Laboratory Values:

LDH:	<input type="text"/> IU/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Hemoglobin:	<input type="text"/> g/dL	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Calcium Level:	<input type="text"/> mmol/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Alkaline Phosphatase:	<input type="text"/> IU/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Sodium, NA:	<input type="text"/> mmol/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
White Cell Count:	<input type="text"/> x 10 ⁹ /L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Neutrophil Count:	<input type="text"/> x 10 ⁹ /L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Platelet Count:	<input type="text"/> x 10 ⁹ /L	(Lower: <input type="text"/> , Upper: <input type="text"/>)
Albumin:	<input type="text"/> g/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)

Please indicate Limits of Normal

If a pre-specified set of normal limits was specified above, check the following box to confirm this set is current:

Pulmonary Function Tests:

Forced Vital Capacity (FVC): . liter **% Predicted FVC:** . %

Forced Expiratory Volume in 1 Second (FEV1): . liter **% Predicted FEV1:** . %

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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)

Pre-Treatment/Evaluative Laboratory Values International Association for the Study of lung Cancer Data Elements for Prospective Lung Staging Project			Logged in: Joan Smith (31023)
Subject ID: 10010001	Code: DLS	Institution: University of Michigan	
Please indicate the type of units used for the laboratory values: <input type="text" value="Conventional Units"/>			
Sex: <input type="radio"/> Male <input type="radio"/> Female	Apply the Following Set of Normal Limits:		<input type="text"/>
Laboratory Values:		Please indicate Limits of Normal	
LDH:	<input type="text"/> IU/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Hemoglobin:	<input type="text"/> g/dl	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Calcium Level:	<input type="text"/> mg/dl	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Alkaline Phosphatase:	<input type="text"/> IU/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Sodium, NA:	<input type="text"/> mEq/L	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
White Cell Count:	<input type="text"/> x 10 ³ /mm ³	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Neutrophil Count:	<input type="text"/> x 10 ³ /mm ³	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Platelet Count:	<input type="text"/> x 10 ³ /mm ³	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
Albumin:	<input type="text"/> g/dl	(Lower: <input type="text"/> , Upper: <input type="text"/>)	
If a pre-specified set of normal limits was specified above, check the following box to confirm this set is current: <input type="checkbox"/>			
Pulmonary Function Tests:			
Forced Vital Capacity (FVC):	<input type="text"/> . <input type="text"/> liter	% Predicted FVC:	<input type="text"/> . <input type="text"/> %
Forced Expiratory Volume in 1 Second (FEV1):	<input type="text"/> . <input type="text"/> liter	% Predicted FEV1:	<input type="text"/> . <input type="text"/> %
<input type="button" value="Submit"/> <input type="button" value="Cancel"/>		eCRF Version: 1.0	

18.5 Disease Description at Diagnosis (Continued)

If histologic type is 'Small cell carcinoma (or combined SCLC),' 'Large cell neuroendocrine (or combined LCNEC),' 'Mixed other,' or 'Other,' please specify the histologic type(s):

If histologic type is 'Small cell carcinoma (or combined SCLC),' please complete the following:

Extent of Disease: Limited disease Extensive disease No data on extent

Paraneoplastic syndrome: Yes No No data

If yes, please complete the following:

SIADH: Yes No No data

Ectopic ACTH: Yes No No data

Myasthenic Syndrome (LEMS, ELS): Yes No No data

If histologic type is 'Small cell lung cancer (or combined SCLC),' 'Large cell neuroendocrine (or combined LCNEC),' 'Carcinoid - typical,' 'Carcinoid - atypical,' 'Carcinoid - not otherwise specified,' or 'Carcinoid-like tumourlet (<0.5 cm),' please complete the following:

Chromogranin: Positive Negative Equivocal/No data

Synaptophysin: Positive Negative Equivocal/No data

CD56: Positive Negative Equivocal/No data

Submit

Cancel

eCRF Version: 1.0

