

## Overview of Respiratory Network sites – What are our capabilities?

**Unit: Department of Respiratory Medicine L – Clinical Research**

**Hospital: Bispebjerg Hospital**

**Date: 15 aug 2014**

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| <b>Staff and Training</b>                                                         |     |           |    |
|-----------------------------------------------------------------------------------|-----|-----------|----|
|                                                                                   | YES | #(number) | NO |
| Experienced study nurses at site                                                  | x   | 2         |    |
| GCP trained nurses                                                                | x   | 2         |    |
| Experienced sub-investigators at site                                             | x   | 4-5       |    |
| GCP-trained investigators                                                         | x   | 2         |    |
| Availability of additional resources in case of e.g. need for unblinded personnel | x   | 4         |    |
| Personnel trained and experienced in quit-smoking counseling                      | x   | 2         |    |

| <b>Clinical Trial Experience</b>                    |     |           |    |
|-----------------------------------------------------|-----|-----------|----|
|                                                     | YES | #(number) | NO |
| Phase 1 (# past 5 years)                            | x   | 1         |    |
| Phase 2 (# past 5 years)                            | x   | 4         |    |
| Phase 3 (# past 5 years)                            | x   | 12        |    |
| Phase 4 (# past 5 years)                            | x   | 3         |    |
| Experience with infusion in trials (# past 5 years) |     |           | x  |

| <b>Experience with Assessments/Procedures</b><br>(tick all that apply) |     |    |                            |                                                          |
|------------------------------------------------------------------------|-----|----|----------------------------|----------------------------------------------------------|
|                                                                        | YES | NO | Site has equipment at site | Site can insource other department/ local lab to perform |
| Spirometry testing (meeting ATS/ERS requirements)<br>e.g.              | x   |    | x                          |                                                          |
| Masterscope                                                            | x   |    | x                          |                                                          |
| Flowscreen                                                             | x   |    |                            |                                                          |
| Threadmill exercise test<br>VO <sub>2max</sub>                         | x   |    |                            | x                                                        |
| Bike exercise test VO <sub>2max</sub>                                  | x   |    | x                          |                                                          |
| 6MWT                                                                   | x   |    |                            |                                                          |
| Incremental and Endurance shuttle walk test                            | x   |    |                            |                                                          |
| X-ray                                                                  | x   |    |                            | x                                                        |
| HRCT scanning                                                          | x   |    |                            | x                                                        |
| Body box/ plethysmography                                              | x   |    | x                          |                                                          |
| Diffusion capacity test - DLCO                                         | x   |    | x                          |                                                          |
| ECG                                                                    | x   |    | x                          |                                                          |
| FENO                                                                   | x   |    | x                          |                                                          |
| Alveolar NO                                                            | x   |    | x                          |                                                          |
| Nasal NO                                                               | x   |    | x                          |                                                          |
| Skin prick test                                                        | x   |    | x                          |                                                          |
| Methacholine test/histamine test                                       | x   |    | x                          |                                                          |
| Mannitol test                                                          | x   |    | x                          |                                                          |
| Exercise-asthma test                                                   | x   |    | x                          |                                                          |
| Bronchoscopy                                                           | x   |    |                            | x                                                        |
| FOT (Forced Oscillation Test)                                          | x   |    | x                          |                                                          |
| Eucapnic hyperventilation test                                         | x   |    | x                          |                                                          |
| CO measurement                                                         | x   |    | x                          |                                                          |
| Induced sputum, Easyneb                                                | x   |    | x                          |                                                          |
| Nasal lavage/ nasal irrigation                                         | x   |    | x                          |                                                          |
|                                                                        |     |    |                            |                                                          |
|                                                                        |     |    |                            |                                                          |

| <b>Facility</b>                                   |     |    |
|---------------------------------------------------|-----|----|
|                                                   | YES | NO |
| Separate and locked room for IMP                  | x   |    |
| Possibility for temperature monitoring of IMP yes | x   |    |
| Room for Monitor                                  | x   |    |

| <b>Other Procedures</b>                                                            |     |    |
|------------------------------------------------------------------------------------|-----|----|
|                                                                                    | YES | NO |
| Availability of written SOP procedure for study procedures (e.g. informed consent) |     |    |
| Possibility of 24 h visits                                                         | x   |    |
| Possibility of 24h PK sampling                                                     | x   |    |
| Establishment of databases                                                         |     |    |
| Establishment of biobanks                                                          |     |    |
| Satellite sites                                                                    |     |    |
| Possibility of archiving of study material for 15 years                            |     | x  |

| <b>Laboratory</b>                                |     |    |                            |                                                          |
|--------------------------------------------------|-----|----|----------------------------|----------------------------------------------------------|
|                                                  | YES | NO | Site has equipment at site | Site can insource other department/ local lab to perform |
| Refrigerator                                     | x   |    | x                          |                                                          |
| with temp monitoring                             | x   |    |                            |                                                          |
| Freezer – 20 degrees                             | x   |    | x                          |                                                          |
| with temp monitoring                             | x   |    |                            |                                                          |
| Freezer – 80 degrees                             | x   |    | x                          |                                                          |
| with temp monitoring                             | x   |    |                            |                                                          |
| Local lab for blood sample analysis              | x   |    |                            | x                                                        |
| Local lab certification                          | x   |    |                            |                                                          |
| IATA certification for handling dry ice shipment |     |    |                            |                                                          |

|                                                        |   |  |  |  |
|--------------------------------------------------------|---|--|--|--|
| Experience in collaboration with external/central labs | x |  |  |  |
| Induced sputum, analysis                               | x |  |  |  |
| Centrifuge                                             | x |  |  |  |
| Cooling centrifuge                                     | x |  |  |  |

| Data Recording                     |     |    |         |
|------------------------------------|-----|----|---------|
|                                    | YES | NO | Comment |
| Experience in use of e-CRF         | x   |    |         |
| Experience in use of e-diaries e.g | x   |    |         |
| AM3                                | x   |    |         |
| Log pad                            | x   |    |         |
| Experience in use of MoveMonitor   | x   |    |         |

| IT                                                                                                               |     |    |         |
|------------------------------------------------------------------------------------------------------------------|-----|----|---------|
|                                                                                                                  | YES | NO | Comment |
| Availability of back up plan in case of crash                                                                    | x   |    |         |
| Own computers, high speed internet                                                                               | x   |    |         |
| Internal firewalls                                                                                               | x   |    |         |
| Wireless internet connection                                                                                     | x   |    |         |
| Electronic medical record system                                                                                 |     | x  |         |
| Electronic medical record system – <b>certified</b> (need of passwords, CRA only access to certain patients etc) |     | x  |         |

**Other Comments:**