Format for application for collection and storage of samples from a new study by IVRN

Study title: A descriptive title of the study.

Investigator(s) and institution(s): Name, address, telephone and fax numbers, as well as e-mail address of the proposing investigator(s)

Study or sub-study rationale: A concise outline of the rationale for the application, including sufficient background information (e.g., data, references, etc.) to support both the scientific merits and the strategic importance of the proposed sample collection.

Study objective(s): A statement of the specific aims of the proposed sample collection.

Study design: A description of the overall design of the clinical trial or cohort study.

Study site(s): Specify the recruitment site(s) for the study and indicate the proximity to Tier 1 laboratory venue(s) (See Appendix 1).

Subjects: A description of the number of planned subjects and their disease characteristics.

Samples: A detailed description of the proposed sampling timepoints in relation to the study timeline (baseline, one month, etc) and to study interventions (pre-drug, on-drug, 12 month follow-up), and a detailed description of the sample characteristics, including sample type (serum, plasma, PBMC, liver), proposed labelling (study ID, etc) and sample quantity.

Collection and transport: A detailed description of where and when (i.e time of day) the samples will be collected and how they will be transported to the Network collection laboratory (Appendix 6.1 for proforma)

Planned assays: A description of assays by the investigators utilizing the samples collected via the Network (if any). Note that an application to the Network for access to the samples is required.

Ethics: Indicate whether institutional ethics committee approval for the study and sample collection has been obtained (see Appendix 6.2 for the ethics approval process)

Funding: Indicate funding source(s) for the study and the available contribution to costs for this specimen collection (if any).

Timelines: Indicate the likely start date and completion date for the study.

Sample sharing arrangements: Clarify the extent to which samples and clinical data will be shared or made available to the IVRN. Potential options are below:

a. Making selected PBMC/serum samples from the whole subject group fully available to the IVRN (e.g. one aliquot available from each timepoint, or all samples from a timepoint, such as week 12 and late follow up)

b. Make all samples from selected subjects fully available to the IVRN (e.g. from subjects not of interest to the primary project)

c. Other alternatives, you may wish to propose (e.g. all samples retained by the investigators of the study before being made fully available to the IVRN after 12 months)

Signature of investigator(s) and date.