INVESTIGATOR SITE FILE

***Delete if not applicable**

Study title	REQUITE: Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life in cancer survivors.
Co-ordinator	Professor Catharine West, University of Manchester, UK
Observational Study Lead	Professor Dr. Jenny Chang-Claude, German Cancer Research Center (DKFZ), Germany
Principal Investigator	
Study Site	
Sponsor*	

Section	Details
1	**REQUITE Observational Study Documentation Set cover page**
2	**Protocol and Patient Information** • RQ0 Study Protocol • RQ1a Current Patient Information Sheet (PIS) (on hospital headed paper) • RQ1b Consent Form (on hospital headed paper) • Family doctor letter (on hospital headed paper)* • Previous (superseded) versions of this documentation
3	**Approvals** • Ethics approval for current protocol and any amendments • R&D approval for current protocol and any amendments* • Other applicable approvals*
4	**Administration** • Signed agreements between involved parties e.g. with third parties recruiting patients* • Sponsorship agreement/sponsorship letter* • Financial information/ budget/ award letter • Insurance statement*
5	**Screening log and Consent forms** • RQ3 Screening and Recruitment Log (or a file note stating where the secure electronic file is stored) • Original copies of signed patient consent forms (or a file note to state where signed forms are located)

6	**Research Team – Staff and Training** • Signed & dated CVs for research team* • RQ4 Delegation Log
7	**Site Initiation & Monitoring** • Signed pre-site initiation checklist • Signed off site initiation checklist • Database sign off sheet • Monitoring documents
8	**Blood collection and Lab Manual** • RQ2 Blood Collection Form • RQ5 Blood Collection and Storage SOP • RQ6 Sample Kits and Courier Shipping SOP • RQ7 Radiation Induced Lymphocyte Assay SOP* • RQ8 Sample Tracking Log (or a file note stating where the secure electronic file is stored) • RQ9 RILA Processing Record* • RQ10a Sample Kit Request Form (and RQ10b Off Project Sample Kit Request Form*) • Confirmation from CIGMR for the receipt of EDTA samples • Previous (superseded) versions of lab manual SOPs
9	**Database and Case Report Forms** • RQ11 Database Manual • Sample copy of all CRFs (breast*, prostate*, lung*) • Completed paper CRFs (or a file note to document where paper copies are located if not completed electronically)* • RQ12 Breast Photographic Assessment SOP*
10	**Reports** • Annual progress reports (ethics)* • Final study report (after completion)*
11	**General correspondence**