Guideline Number	**51.001A**	Version	**1.0**	
Title	**Sponsor Protocol Review Checklist**			

Study title:			
Sponsor(s):		**R&I Ref:**	
Chief Investigator:		**IRAS No:**	

	Included:			Comments
	Yes	No	N/A	
Section 1: General Protocol Information and Document Control				
Protocol title is consistent with IRAS and supporting documents	☐	☐		
Version number and date clearly stated (starting V1.0)	☐	☐		
Version history included or documented	☐	☐		
Page numbering included (e.g. Page X of Y)	☐	☐		
Sponsor(s) named consistently throughout the protocol and Sponsor reference	☐	☐		
Funder(s) named, finance provided and reference (any in-kind contributions should also be stated)	☐	☐	☐	
CI and overall study responsibilities clearly described	☐	☐		
CI and Sponsor representative signature (and co-Sponsor signature where applicable)	☐	☐		
Relevant study contacts included	☐	☐		
Public registration stated (ISRCTN, ClinicalTrials.gov, etc.) and reference where required (see SOP 51.017)	☐	☐	☐	
Section 2: Study Design and Conduct				
Primary research question is clearly defined	☐	☐		
Study design clearly described (e.g. observational, interventional, feasibility, open-label, blinded etc.)	☐	☐		
Key risks to participant safety and data integrity identified and mitigations within the study design	☐	☐		
Trial rationale and hypothesis defined	☐	☐		
Clearly defined objectives in this section with primary and secondary outcomes identified	☐	☐	☐	
For CTIMPs, describe prior experience in disease area and dose selection of IMPs if applicable.	☐	☐	☐	
Randomisation procedures described where relevant	☐	☐	☐	
Protocol describes what research activities distinct from standard care	☐	☐	☐	
Inclusion and exclusion criteria are clearly stated	☐	☐		
Sample size and recruitment targets clearly described	☐	☐		
Expected duration of participant involvement stated	☐	☐	☐	
Schedule of Procedures/ Assessments included for interventional studies with an appropriate visit window defined	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Planned follow-up after end of study described (if applicable)	☐	☐	☐	
Study design and procedures are feasible within proposed setting and resources	☐	☐		
Appropriate references or supporting evidence included where relevant	☐	☐	☐	
Section 3: Recruitment and Participant Identification (if applicable) N/A ☐				
Recruitment pathway clearly described	☐	☐	☐	
Clear description of screening procedures (inc. documentation) and screening responsibilities clearly defined (e.g. care team vs research team)	☐	☐	☐	
Use of clinical records or databases appropriately described	☐	☐	☐	
Governance arrangements for database access described	☐	☐	☐	
Use of Participant Identification Centres (PICs) described where relevant	☐	☐	☐	
Consent process is clearly described (including personnel, timing and setting) see SOP 51.002	☐	☐	☐	
Appropriate alternative methods for supporting the informed consent process specified e.g. translators, PIS in other languages.	☐	☐	☐	
Process for documenting consent is described (e.g. written/electronic consent, records)	☐	☐	☐	
Arrangements for ongoing consent / re-consent described	☐	☐	☐	
Participant withdrawal process clearly described (how to withdraw and who to contact)	☐	☐	☐	
Distinction between withdrawal from treatment vs withdrawal from study is clear (if applicable)	☐	☐	☐	
Co-enrolment (participation in other studies) is addressed (allowed, restricted, or managed) and risk described where relevant	☐	☐	☐	
Section 4: Roles, Responsibilities and Sponsorship				
Sponsor correctly identified and appropriate for study	☐	☐		
Co-sponsorship or joint sponsorship clearly described (if applicable)	☐	☐	☐	
Allocation of sponsor responsibilities documented where co-sponsored	☐	☐	☐	

	Included:			Comments
	Yes	No	N/A	
PI location responsibilities clearly described (for multi-location studies)	☐	☐	☐	
Sponsor oversight arrangements described (see QA section)	☐	☐		
Insurance / indemnity arrangements stated and appropriate	☐	☐		
Section 5: Data Management and Data Protection				
Data to be collected clearly described	☐	☐		
Processes ensure data is accurate, complete and verifiable	☐	☐		
Description of data flow and in what form i.e. identifiable vs pseudonymised vs anonymous data clearly stated (for both electronic data and paper records)	☐	☐		
Data Controller(s) clearly identified and consistent with IRAS, specify any plans for transfer of data controllership following study completion	☐	☐		
Data custodian identified and responsibilities for data management clearly described	☐	☐		
Data access restricted to appropriate study personnel	☐	☐		
Data storage locations at each stage identified and appropriate	☐	☐		
Data transfer to third parties described (if applicable)	☐	☐	☐	
Plan or potential for future data use described	☐	☐	☐	
Governance approvals identified where identifiable data used (e.g. DPIA, Caldicott)	☐	☐	☐	
Arrangements for confidentiality and security clearly described	☐	☐		
Data retention and archiving arrangements described	☐	☐		
Section 6: Data Analysis and Statistics				
Statistician or researcher undertaking analysis named, if possible, and responsibilities outlined	☐	☐		
Objectives and endpoints are clearly defined and consistent	☐	☐		
Sample size justification provided (or feasibility rationale if applicable)	☐	☐		
Planned analysis methods are described (proportionate to study)	☐	☐		
Handling of missing data described where relevant	☐	☐		
Statistical analysis plan described (or SAP referenced) where required	☐	☐	☐	

	Included:			Comments
	Yes	No	N/A	
Section 7: Samples, Tissue and Analysis (if applicable) N/A ☐				
Collection of biological samples described	☐	☐	☐	
Processing and analysis of samples described (must be categorised and accompanying sample handling and lab manuals produced – see SOP 51.028, 51.029 & 51.030)	☐	☐	☐	
Storage location and retention period for samples stated	☐	☐	☐	
Arrangements for future storage and/or sharing, as well as future use of samples described	☐	☐	☐	
Rights to withdraw samples explained	☐	☐	☐	
Genomic analysis identified and any additional consents required documented where applicable	☐	☐	☐	
Section 8: Imaging (if applicable) N/A ☐				
Use of imaging within the study is clearly identified (e.g. CT, MRI, PET, X-ray, ultrasound)	☐	☐	☐	
Purpose of imaging within the study clearly stated (e.g. diagnosis, outcome measure, safety monitoring)	☐	☐	☐	
Distinction between standard care imaging and research-specific imaging is clear	☐	☐	☐	
Applicable regulatory requirements identified (e.g. IR(ME)R where ionising radiation used)	☐	☐	☐	
Requirement for specialist review identified (e.g. medical physics / radiation expert where applicable)	☐	☐	☐	
Additional risks from research-specific imaging clearly described	☐	☐	☐	
Radiation exposure (where applicable) justified and minimised	☐	☐	☐	
Imaging procedures clearly described (what, when, how often)	☐	☐	☐	
Imaging data flow is clearly defined and distinction between clinical reporting and research analysis is clear	☐	☐	☐	
Section 9: Safety Reporting (if applicable) N/A ☐				
Safety reporting procedures clearly described (AE/SAE/SUSAR/USM as applicable).	☐	☐	☐	
Roles and responsibilities for safety reporting defined (PI / CI / Sponsor).	☐	☐	☐	
Timelines for reporting clearly described and compliant with regulations.	☐	☐	☐	
Procedures for urgent safety measures described where applicable	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Incidental finding reporting process detailed where applicable	☐	☐	☐	
Pregnancy reporting requirements detailed	☐	☐	☐	
Section 10: Device Studies (CIMDs and Non-Regulated) (if applicable) N/A ☐				
Device involvement clearly identified (regulated clinical investigation vs non-regulated use)	☐	☐	☐	
Applicable regulatory pathway correctly identified (e.g. MHRA device investigation vs non-regulated study)	☐	☐	☐	
Device classification (CE/UKCA marked, class, investigational) clearly described	☐	☐	☐	
Intended use aligns with licensing status (on-label vs off-label)	☐	☐	☐	
For non-regulated studies, justification provided for why MHRA authorisation is not required	☐	☐	☐	
Risks associated with device/software/AI use are identified and Risks associated with device use are clearly identified and proportionate	☐	☐	☐	
Device use within the study is clearly described (who uses it, how, and when)	☐	☐	☐	
Training requirements for staff and participants or carers (if applicable) using the device are described	☐	☐	☐	
Safety monitoring arrangements appropriate to device risk are described	☐	☐	☐	
Procedures for device malfunction or incident management are described	☐	☐	☐	
Device supply, storage and accountability arrangements described	☐	☐	☐	
Device traceability arrangements in place (e.g. serial/batch tracking where required)	☐	☐	☐	
Relevant supporting documentation available (e.g. Instructions for Use, technical file, risk assessment)	☐	☐	☐	
Maintenance, calibration and servicing requirements described (where applicable)	☐	☐	☐	
Data collected from the device is appropriate, reliable and usable for analysis	☐	☐	☐	
Section 11: AI and Software Integration (SaMD and Non-Regulated) (if applicable) N/A☐				
Use of AI/software within the study is clearly identified	☐	☐	☐	
Role of AI/software is clearly described (e.g. decision support, data analysis, diagnostic, monitoring)	☐	☐	☐	

	Included:			Comments
	Yes	No	N/A	
How the AI/software is used within the study (who, when, how) is clearly described	☐	☐	☐	
Appropriate level of human oversight is described	☐	☐	☐	
Users are appropriately trained to use and interpret outputs	☐	☐	☐	
Risks associated with AI/software use (e.g. incorrect outputs, misclassification) are identified	☐	☐	☐	
Potential for bias, error or variability in outputs has been considered	☐	☐	☐	
Process for managing system errors, failures or unexpected outputs is defined	☐	☐	☐	
Approach to software/AI validation or performance assurance is described	☐	☐	☐	
Evidence supporting performance (e.g. prior testing, validation data) is referenced where available	☐	☐	☐	
Updates or version changes to software are controlled and documented	☐	☐	☐	
Data inputs to the AI/software are appropriate and clearly defined	☐	☐	☐	
Outputs are clearly defined and aligned with study objectives/endpoints	☐	☐	☐	
Distinction between raw data, processed outputs and clinical decisions defined	☐	☐	☐	
Section 12: Investigational Medicinal Products (IMPs)/Medicines (if applicable) N/A ☐				
Study correctly classified as CTIMP or non-CTIMP involving medicines (including off-label use)	☐	☐	☐	
IMP(s) clearly defined (name, formulation, dose, route). For IMPs that are used as part of a regimen e.g. within cancer trials, the regimen must be clearly defined	☐	☐	☐	
Licensing status of IMP(s) clearly described (licensed / unlicensed/off-label use/ licensed outwith UK)	☐	☐	☐	
For blinded studies, clearly define if/how matched placebo is being provided	☐	☐	☐	
IMP presentation details clearly described e.g. pack size, strength/concentration, excipients etc.	☐	☐	☐	
Rationale for use of the IMP(s) in the study is clearly described	☐	☐	☐	

	Included:			Comments
	Yes	No	N/A	
IMP administration details clearly described (dose, frequency, route, cycle length, duration). Consider: *For orals*: how should the IMP be taken e.g. with or without food; timing in relation to other medicines; what to do if a dose is missed or vomited up or unable to be swallowed. *For parenteral route*: use of in-line filters; requirement for pre-medication/ supportive therapies; response to allergic reactions/ infusion reactions; acceptable window of administration. Document handling of late or missed doses.	☐	☐	☐	
Dosing method clearly defined e.g. use of Body Surface Area (BSA); weight; use of calculated creatinine clearance; capping of BSA; use of dose banded nomograms.	☐	☐	☐	
Storage, receipt, handling, ordering, dispensing/ preparation and accountability arrangements described. Make reference to IMP Management Manual as applicable.	☐	☐	☐	
Arrangements for supply of IMP(s) defined (e.g. will locations be provided with trial-labelled stock/ commercial stock via Sponsor or will locations use own hospital stock and if so, arrangements for reimbursement, any brand restrictions and are locations expected to ring-fence supplies; is it expected that stock will be stored outwith pharmacy).	☐	☐	☐	
Labelling of the IMP is defined e.g. will locations be expected to add additional labels.	☐	☐	☐	
Known and foreseeable risks of the IMP(s) identified and proportionate	☐	☐	☐	
Supporting documentation referenced (e.g. IB, SmPC) where required	☐	☐	☐	
Preparation and administration of IMPs and training requirements	☐	☐	☐	
For blinded studies, describe Drug Management System that will be used and where to find detailed information. Include information on emergency unblinding including alert cards.	☐	☐	☐	
IMP Toxicity management guidelines included. Factors to consider; levels of dose reduction (and number of reductions before coming off study; when to dose reduce/ delay (temporary stop)/ omit; dose reescalation permitted or not; acceptable treatment breaks for toxicity and non-toxicity reasons; supportive meds to be used to treat toxicities.	☐	☐	☐	
Prohibited meds (include washout periods) and those that should be used with caution clearly defined; consider concomitant use of vaccines.	☐	☐	☐	

	Included:			Comments
	Yes	No	N/A	
Potential drug interactions clearly described and subsequent monitoring parameters included if relevant.	☐	☐	☐	
Pre-treatment assessments and monitoring parameters clearly defined (include window of flexibility)	☐	☐	☐	
Interaction with other therapies e.g. radiotherapy or situations e.g. photosensitivity defined.	☐	☐	☐	
Define if surgery/ radiotherapy is allowed whilst on trial drug.	☐	☐	☐	
Criteria for stopping (permanent withdrawal) of IMP treatment defined.	☐	☐	☐	
Procedures for withdrawal from IMP but continuation in study described.	☐	☐	☐	
Arrangements for assessing IMP compliance are detailed e.g. use of diary cards; return of empty and part-used containers. Actions to be taken on assessing compliance to be documented eg of less than an expected threshold % discuss with PI etc	☐	☐	☐	
Post-trial access to IMP (if applicable) described.	☐	☐	☐	
Trial restrictions including contraception requirements	☐	☐	☐	
If NIMPs have been identified, ensure information as above is clearly defined where relevant.	☐	☐	☐	
Section 13: First-in-Human (FIH) / Early Phase Studies (if applicable) N/A☐				
Study is correctly identified as First-in-Human / early phase (Phase I)	☐	☐	☐	
Rationale for starting dose clearly described and justified	☐	☐	☐	
Dose escalation strategy clearly defined (including increments and sequence)	☐	☐	☐	
Sentinel dosing / staggered dosing approach described where applicable	☐	☐	☐	
Criteria for dose escalation and cohort progression clearly defined	☐	☐	☐	
Dose Limiting Criteria (DLT) are clearly defined and DLT assessment period included	☐	☐	☐	
Maximum Tolerated Dose (MTD) and recommended Phase II dose defined (if applicable)	☐	☐	☐	
Participant evaluability for DLT assessment included	☐	☐	☐	
Predefined stopping rules (safety / escalation halting) clearly described	☐	☐	☐	

	Included:			Comments
	Yes	**No**	**N/A**	
Enhanced safety monitoring arrangements described (e.g. intensive monitoring post-dose)	☐	☐	☐	
Arrangements for medical emergencies and immediate clinical care clearly described	☐	☐	☐	
Study conducted in an appropriate Phase I / suitably equipped setting	☐	☐	☐	
Oversight arrangements for early-phase risk (e.g. Phase 1 committee review, IDMC) described	☐	☐	☐	
Arrangements for Safety Review Committee detailed including membership	☐	☐	☐	
Section 14: Genetically Modified Organism (GMO) / Advanced Therapy (ATMP) Studies (if applicable) N/A☐				
Study correctly identified as involving GMO / ATMP	☐	☐	☐	
Appropriate regulatory pathway and approvals identified (e.g. contained use / deliberate release)	☐	☐	☐	
Environmental risks and mitigations described where applicable	☐	☐	☐	
Containment, handling (on storage and in-use) and disposal procedures for GMO material described	☐	☐	☐	
Assessment of shedding, persistence or transmission risk described	☐	☐	☐	
Storage, transport and traceability arrangements appropriate for GMO material	☐	☐	☐	
Long-term follow-up requirements (if applicable, e.g. gene therapy) described	☐	☐	☐	
Section 15: Quality Assurance, Compliance and Deviations				
Monitoring requirements and responsibilities are clearly described (or justification provided if not required)	☐	☐		
Scope and frequency of monitoring activities are described where applicable or monitoring plan references	☐	☐	☐	
Oversight arrangements described (e.g. Sponsor review, committees, reporting) (see SOP 51.023 and SOP 51.036)	☐	☐		
Arrangements for audit/inspection readiness are described (proportionate)	☐	☐		
Processes for identifying, recording and reporting protocol deviations/ non-compliances/ serious breaches are described as appropriate (see SOP 51.008 and 51.009)	☐	☐		

	Included:			Comments
	Yes	**No**	**N/A**	
Section 16: Ethics, Regulatory and Approvals				
REC requirement correctly identified	☐	☐		
Reviewing REC named (where applicable), prior to or following submission as appropriate	☐	☐	☐	
Correct regulatory pathway identified (e.g. MHRA / combined review)	☐	☐	☐	
IRAS content consistent with protocol	☐	☐		
Study complies with UK Policy Framework principles	☐	☐		
Compliance with applicable regulations stated				
Section 17: Archiving and Study Close-Out				
End-of-study definition clearly stated and appropriate	☐	☐		
Criteria and governance for early study termination described (if applicable)	☐	☐	☐	
Archiving responsibilities clearly defined	☐	☐		
Archiving locations identified	☐	☐		
Retention period appropriate for study type (CTIMP: minimum legal retention acknowledged)	☐	☐		
Plans for dissemination of results are described	☐	☐		
Plan for lay summary or participant-accessible results described	☐	☐	☐	

Guideline signatories

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Document history

Version	Date	Description	Retrospective Implementation
1.0	19/08/2026	First Release	No