Nutrition - UNITED KINGDOM

Competent authority

Contact Details	**Contact Name 1** Medicines & Healthcare products Regulatory Agency **Phone** 020 3080 6456 **Email General** clintrialhelpline@mhra.gsi.gov.uk **Email Department** ris.ct@mhra.gsi.gov.uk **Address** 151 Buckingham Palace Road/ Victoria **ZIP/City** SW1W 9SZ London **Country** United Kingdom (UK) **Web address** https://www.gov.uk/guidance/contact-mhra
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) **Regulatory and ethics bodies involved - Additional information** national or only institutional approval depends on the participants i.e. whether they are ‘patients’ or recruited from the community **CA - Registration requirements for clinical trials** – **CA - Submission required to** National CA Institutional CA **Applicable national legal framework/ Reference** whether national or only institutional approval is required, depends on the participants i.e. whether they are ‘patients’ or recruited from the community
Submission Format	**Standard application form available** Yes **Standard application form** indicates where participants are ‘patients’
Language of Submission	**Language(s) of application** English

Preferred language of application

–

English accepted

Yes

Documents mandatory to be in official national language

–

Documents mandatory to be in local language of study site

–

Documents mandatory to be in language of the study participant

–

Ethics committee

Contact Details

Additional Information

If studies involve patients, an ethics committee allocated through the National Research Ethics service (NRES) will be used. Otherwise, a local Research Ethics Committee (LREC) with the required expertise to assess the project will be responsible. In University settings, the LREC is likely to be an institutional committee.

Ethical Review – General

Submission for Ethical review mandatory for

–

Submission of study mandatory

Yes

Submission to CA and EC to be performed in the following order

–

National declaration on Ethical requirements exists

Yes

National declaration

dsfdf

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Institutional EC

Additional Information

National EC: required if participants are ‘patients’. Otherwise, institutional EC involved

Multi-Centre Studies - Ethical Review

Ethical approval (favourable opinion) required from

Lead EC (authorised to issue a single opinion)
All local ECs of participating sites

Ethical approval - Additional information

Where all sites are within the UK, and the National Research Ethics Service is used, a single ethics committee review would be carried out. Where sites span countries, approval from a UK committee would be required.

For multicentre projects which do not require national ethics review, institutional approval would be sought at each site from the local ethics committee.

Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Physician Dietitian Nutritionist PhD National citizen **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** in case participants are ‘patients’. For research using non-patient participants, individual institutions would use different application forms For all research recruiting participants who are ‘patients’, standard application form can be found at
Language of Submission	**Language(s) of application** English **Preferred language of application** – **English accepted** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 3 **Time in weeks from submission to positive approval (maximum)** 12 **Time in weeks from submission to positive approval (average)** 5
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** – **Responsible for notification of SA** – **Timeline Ethical review of SA (max nr days)** –
Safety Reporting	**Investigator shall report SAE to** Institution, National CA, Sponsor, Trial Coordinator, **Additional Information** In multi-centre trial the coordinating site will be informed

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Co-sponsorship allowed** Yes **Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist Nurse Pharmacist PhD National citizen **Entitled to be principal investigator for trials with patients** – **Entitled to be principal investigator for trials with healthy participants** – **Entitled to be principal investigator for trials with vulnerable population** –
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **Standard IC form (ICF)** Only for patient –related studies **Accepted format of Informed Consent (IC) form** Oral consent Written consent Consent by proxy **Accepted format of IC form for studies including patients** – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Elderly Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners

	Regulations concerning the inclusion or exclusion available Yes **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** Time effort Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel) Phase I trials **Additional Information** Generally, participants in research involving patient groups are not reimbursed. However, they may be offered reimbursement if the research is unrelated to their treatment, e.g. a scientific study investigating metabolism/ nutritional aspects in a pathological state.
Funding	**Trials generally financially supported by industry** Yes **Name of public company/institution supporting financially** Government organisations such as Medical Research Council (MRC), Biotechnology and Biological Sciences Research Council (BBSRC) **Name of private company/institution supporting financially** Charitable institutions such as Wellcome Trust, Dunhill Medical Trust **Name of industry company/institution supporting financially** Food/nutrition related companies such as Unilever, Mars Incorporated, Abbott Nutrition, Nestlé **Funding is an issue during the approval process** No
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers **Name and contact insurance companies insuring clinical research** Several insurance companies appear to offer this policy. An insurance broker would be able to supply range of quotes / companies. **Insurance fee in € value indicated as** –

	Insurance fee for lowest risk research - Additional Information Only information for University of Nottingham available: University of Nottingham has institutional cover for its research activities involving participants, which is not charged at a ‘per person’ rate. **Insurance fee in € value indicated as** – **Insurance fee for highest risk research - Additional Information** Only information for University of Nottingham available: University of Nottingham has institutional cover for its research activities involving participants, which is not charged at a ‘per person’ rate. **Additional Information** Additional information to "Liability insurance or alternative arrangements for damages mandatory for": This may differ from institution to institution. The University of Nottingham hold insurance policies to cover participants, employees and the institution, where they are the designated sponsor. Clinical staff (nurses, doctors and dietitians) employed by the University have to arrange their own professional indemnity. Where University staff are conducting trials with external sponsors (e.g. pharmaceutical company), the participant and sponsor insurance would be arranged by the external sponsor. In the NHS, insurance policies to cover participants, employees and the institution are held. Clinical staff (nurses, doctors and dietitians) employed by the NHS are expected to arrange their own professional indemnity. Where NHS staff are conducting trials with external sponsors (e.g. pharmaceutical company), the participant and sponsor insurance would be arranged by the external sponsor.
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Audits Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF) **Regularly performed methods - Additional information** Monitoring and CRF are required if participants are ‘patients’. Otherwise, audits and SOPs applicable. **Standards concerning quality assurance and quality control exist** Yes **Standards concerning quality assurance and quality control** If participants are ‘patients’. For research using non-patient participants, individual institutions may have different standards. **Regularly performed audits** –
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Yes

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki Other ethical principles for medical research (other than Declaration of Helsinki) ICH-GCP Guidelines International regulatory requirements European regulatory requirements - European Directive 2001/20/EC, 2005/28/EC National regulatory requirements Regional regulatory requirements Institutional regulatory requirements **Applicable national laws** Data protection act, Hospital act (if patients are being recruited), Genetical engineering act (if samples are taken for genetic analysis); **National regulations for volunteers exist for** – **Additional Information** ICH-GCP Guidelines, International, European, National and Regional regulatory requirements applicable if participants are 'patients'. Otherwise, institutional guidelines and regulatory requirements only.
Nutrition	**Nutrition considered as drug** Case by case **Additional Information** Not necessarily. It depends upon the specific aims of the nutritional 'treatment'.
Data Protection	**Specific Requirements** Yes **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Invasive Catheters	**Invasive catheters permitted** Not specified

Definition

Observational Study	**Definition in national law** No specific definition of an observational study in respect to a nutritional epidemiology exists, but within the EC guidelines a definition of an 'observational study' is A study where any medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data (as per Article 2(c) of 2001/20/EC).