Nutrition/Interventional - UNITED KINGDOM

Competent authority

Contact Details	**Contact Name 1** Medicines and Healthcare Products Regulatory Agency **Phone** Tel. +44 (0)20 3080 6000 **Email General** info@mhra.gsi.gov.uk **Address** Buckingham Palace Road Victoria 151 **ZIP/City** SW1W 9SZ London **Country** United Kingdom (UK) **Web address** http://www.mhra.gov.uk
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) **Regulatory and ethics bodies involved in approval process for trials including patients** Institutional CA **Regulatory and ethics bodies involved in approval process for trials including including healthy participants** Institutional EC **Regulatory and ethics bodies involved in approval process for trials including vulnerable population** Medicines Agency Competent Authority/-ies (CA) Ethics committee(s) **Regulatory and ethics bodies involved - Additional information** Medicines Agency could be required if nutritional intervention was categorised as ‘treating’ a disease National or only institutional EC and CA approval depends on the participants i.e. whether they are ‘patients’ or recruited from the community **CA - Registration/ notification without approval required for** – **CA - Registration requirements for clinical trials** –

Registration requirements for clinical trials including patients

–

Registration requirements for clinical trials including healthy participants

–

Registration requirements for clinical trials including vulnerable population

–

Registration requirements - Additional information

Although not ‘mandatory’ for UK governance authorities, registration of nutritional studies (observational and interventional studies) is recommended due to publication requirements.

CA - Submission required to

Institutional CA

Studies including patients - submission required to

National CA

Studies including healthy participants - submission required to

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Studies including vulnerable population - submission required to

whether national or only institutional approval is required, depends on the participants i.e. whether they are ‘patients’ or recruited from the community

Additional Information

Studies including vulnerable population - submission required to: 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

if participants are ‘patients’

Language of Submission

Language(s) of application

English

Language(s) of application for trials including patients

–

Language(s) of application for trials including healthy participants

–

Language(s) of application for trials including vulnerable population

–

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

–

Timelines Authorisation

Time to approval of CA in weeks (minimum)

3

Time to approval of CA in weeks (maximum)

6

Additional Information

Time to approval in case nutrition is considered as pharmaceutical/drug.

Research Governance Department at the University of Nottingham usually take 7-14days to approve a protocol for studies requiring NRES ethical review (studies involving patients and drug trials).

Research Governance in the NHS (R&D departments in individual hospitals) can take up to 12 weeks to approve a study involving patients / use of hospital (NHS) facilities, but this will depend upon institution and complexity of trial.

If support/resources are sought from national research networks, this can take 6-12wks to be negotiated. However, this approval process usually runs in parallel to the R&D process, so shouldn't add to the study set-up time.

Ethics 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

National Declaration
Code of research conduct and research ethics (Institutional Declaration)

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

–

Ethical approval (favourable opinion) for trials including patients to be obtained from

Central EC

Ethical approval (favourable opinion) for trials including healthy participants to be obtained from

Institutional EC

	Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from National EC approval required if vulnerable population are considered as patients. **Additional Information** Trials including vulnerable popultion: National EC approval required if vulnerable population are considered as patients.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) Any accredited EC **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** – **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 Investigator Physician Dietitian Nutritionist PhD Industry National citizen **Entitled to submission of trials including patients** – **Entitled to submission of trials including healthy participants** same as above. But application is limited to institution **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** – **Additional Information** Industry may submit the application to the EC in case particiants are patients; or if the intervention is defined as a ‘drug trial’. Otherwise, collaborators submit to their institutional ethics committee
Submission Format	**Standard application form** Standard Application Form for patients

Language of Submission	**Language(s) of application** English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **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 study participant** –
Safety Reporting	**Investigator shall report SAE to** – **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Co-sponsorship allowed** Yes **Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** – **Entitled to be principal investigator for trials with patients** Physician

	Entitled to be principal investigator for trials with healthy participants Physician Dietitian Nutritionist Nurse Pharmacist PhD National citizen **Entitled to be principal investigator for trials with vulnerable population** Physician Dietitian Nutritionist Nurse Pharmacist PhD National citizen
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Yes **Standard IC form (ICF)** NHS: Search for ‘consent forms’ and filter by ‘documents’ Nottingham University: institutional form can be found **Standard ICF - Additional Information** A standard informed consent form exists for nutrition intervention in patients and in vulnerable groups if participants are ‘patients’. For research using non-patient participants, individual institutions may use different consent forms **Accepted format of Informed Consent (IC) form** Written consent **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** – **Accepted format of patient consent - Additional information** Where a participant is unable to provide written consent, witnessed, oral consent is acceptable. Where a trial is studying patients who are unable to give consent (e.g. unconscious trauma patients), consent is usually obtained from a proxy (e.g. next of kin) and consent for continued inclusion in the trial would be obtained from the patient as soon as their medical condition enabled this. (see vulnerable groups)
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

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Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Optional

Reimbursement for patients

–

Reimbursement for healthy participants

–

Reimbursement for vulnerable population

–

Compensation is limited to/provided for

Time effort
Inconvenience, Pain, Discomfort
Expenses arising from study participation (e.g. Travel)
Phase I trials

Compensation for patients is limited to/provided for

–

Compensation for healthy participants is limited to/provided for

–

Compensation for vulnerable population is limited to/provided for

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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.

Compensation of time efforts or inconvenience / pain / discomfort in patients or vulnerable population is only applicable where research study is unrelated to treatment/ usual care.

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

Yes

	Additional Information Ethics Committee fees may be levied where there is an industrial sponsor and the work is evaluating the sponsor's product (including, but not confined to medicinal products).
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Recruitment process** There are ethical guidelines regarding how to recruit individuals without coercion, inducement etc. but not national regulations (uncertain). **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Differs by institution **Obligation to contract a liability insurance for trials including patients for** Patients/Volunteers **Obligation to contract a liability insurance for trials including healthy participants for** – **Obligation to contract a liability insurance for trials including vulnerable population for** – **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 € for lowest risk research (minimum)** 0 **Insurance fee in € value indicated as** – **Insurance fee for lowest risk research - Additional Information** 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** University of Nottingham has institutional cover for its research activities involving participants, which is not charged at a 'per person' rate.

Additional Information

Liability insurance or alternative arrangements for damages for patients / researchers: 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

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Regularly performed methods in trials including patients

Audits
Monitoring
Standard Operating Procedures (SOP)

Regularly performed methods in trials including healthy participants

Audits
Standard Operating Procedures (SOP)

Regularly performed methods in trials including vulnerable population

Monitoring
Case Report Form (CRF)

Regularly performed methods - Additional information

In case of trials including vulnerable population: Monitoring and CRF required if participants are ‘patients’. Otherwise, as for ‘nutritional intervention (in healthy people)’

Standards concerning quality assurance and quality control exist

Yes

Standards concerning quality assurance and quality control

Standards exist for interventional trials in patients and vulnerable groups in case they are considered as patients. For research using non-patient participants, individual institutions may have different standards.

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

–

Regularly performed audits in trials including vulnerable population

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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

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Applied regulatory conventions in studies including patients

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)
ICH-GCP Guidelines

Applied regulatory conventions in studies including healthy participants

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)
Other guidelines for good clinical practice (other than ICH-GCP)

Applied regulatory conventions in studies including vulnerable population

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

Applicable national laws

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Applicable national laws for patients

Hospital Act, Data protection Act, Genetical engineering act (If samples are taken for genetic analysis), Medical device act (If a medical device is being tested),

Applicable national laws for healthy participants

Data protection Act, Genetical engineering act (If samples are taken for genetic analysis), Medical device act (If a medical device is being tested),

Applicable national laws for vulnerable population

Hospital Act (If patients are being recruited), Data protection Act, Genetical engineering act (If samples are taken for genetic analysis), Medical device act (If a medical device is being tested);

National regulations for volunteers exist for

Isotopes
Tissue samples

Additional Information

Applied regulatory conventions in studies including vulnerable population: required 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'.
Blood & Tissue Samples	**Tissue samples permitted** Yes
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)** –

Definition

Interventional Study	**Definition in national law** From definitions of clinical trials; Interventional studies include all trials based on random allocation of interventions and also non-randomised interventions where participants or groups of participants are given treatments (of whatever nature) that they would not otherwise be receiving in the ordinary course of events and which are allocated by the investigators.