Integrated Research Application System (IRAS)

Collated Question-specific guidance for Project Filter

The following document collates all guidance for the questions in Project Filter.

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The short title of the research

- The program automatically uses this to create a "header" throughout the form. The applicant should include a version number as part of the short title to help the identification of documentation approved and the future monitoring of the application.

- Use this title consistently in all information sheets and consent forms for research participants or others giving consent on their behalf. It must be sufficiently detailed to make clear to participants what the research is about. If acronyms are used the full title should explain them.

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Research or audit/service evaluation

Where a project is not classified as research, all potential applications in IRAS are disabled except those to the Confidentiality Advisory Group (CAG; see note below). Applications to other bodies are required only where a project is considered to be research.

The UK Policy Framework for Health and Social Care Research sets out the responsibilities and standards that apply to work managed within the formal research context. It defines 'research' as "The attempt to derive generalisable or transferable new knowledge" (see paragraph 3.1 for more details).

Although some research projects include evaluation, where a project is considered to be **solely** audit or service/therapy evaluation, it will not be managed as research within the NHS or social care.There is no need to submit applications in IRAS.

Differentiating research, audit and service evaluation

The Health Research Authority (HRA) has prepared some simple guidance for researchers in the form of a decision tool, which is available at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

The decision tool is for use by applicants and R&D offices in assessing whether or not a project should be classified and managed as research. If in doubt, you may consult your R&D office, or email the HRA Queries Line at queries@hra.nhs.uk.

Additional guidance on the characteristics of research in the social care setting is available via the HRA website page for Social Care Research .

If after discussion the project is considered to be research, reply "Yes" to sieve question 1 and proceed with your application(s).

If the project is solely audit or service evaluation, or some other type of non-research activity such as case study, system/equipment testing or satisfaction survey, you should check with the NHS clinical governance office or local authority what other review arrangements or sources of advice apply to the project. For example, there may be standard guidelines on the conduct of clinical audit. The Caldicott Guardian of Local Authority Information Governance Lead will be a source of advice on the use of patient or service user data.

Confidentiality Advisory Group (CAG)

If you are conducting an audit, service evaluation or other non-research activity with a medical purpose and the project will involve use of identifiable patient data without explicit consent, you may need to apply for support under Section 251 of the NHS Act 2006.

Please see https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/ for further guidance.

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Clinical trials of investigational medicinal products (CTIMPs)

IMPORTANT:

It is no longer possible for CTIMP applications to be made using this part of IRAS. If you have an existing CTIMP project and have not yet submitted your MHRA Medicines, IRAS, REC or GTAC forms (as applicable), you will no longer be able to do so here.

All CTIMPs now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

If you are already preparing a combined review application and your project will involve either ionising radiation or an investigational medical device, please refer to IRAS Help guidance.

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Clinical investigations or other studies of medical devices

This option should be selected for any clinical investigation or other research study of a medical device. Further questions will appear to identify the type of study and generate the appropriate version of the form.

Do not select this option where the research protocol involves use of a UKCA/CE UKNI/CE

marked device within its intended purpose *but is not designed to investigate the device itself*.

Please note that from 26 May 2021, studies taking place in Northern Ireland, which involve CE-marked devices and procedures that are additional to the normal conditions of use of the device, may need to apply to MHRA Devices. Please refer to the further guidance provided against the sub-category options and against the MHRA Devices Form option at filter question 4.

Pilot of coordinated assessment pathway for clinical investigations of medical devices: the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) are working together to test a coordinated assessment pathway that will streamline the review of clinical investigations of medical devices. To find out more and register your interest visit the MHRA website.

Guidance last updated: 30 July 2021

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Clinical trial of a drug/device combination (IMP/Device Trial)

IMPORTANT:

It is no longer possible for a new combined trial of an investigational medicinal product and an investigational medical device (IMP/Device trial) application to be made using this part of IRAS. If you have an existing IMP/Device project and have not yet submitted your MHRA Medicines, IRAS, REC or GTAC forms (as applicable), you will no longer be able to do so here.

All new IMP/Device trial applications should now now need to apply using the combined review service. Please follow the process outlined in IRAS Help.

Guidance last updated: 28 February 2022

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Other clinical trials or clinical investigations

This option should be selected for clinical research not involving investigational medicinal products

or medical devices.

For example, this option would be appropriate for research involving:

- Surgery
- Radiotherapy
- Imaging investigations
- Mental health investigations or therapies
- Physiological investigations
- Trials of products not defined as medicines or medical devices (e.g. nutritional)
- Complementary or alternative therapies

Medicinal research

If you are unsure whether your research is subject to the Medicines for Human Use (Clinical Trials) Regulations 2004, please consult the detailed guidance on the MHRA website at:

https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

Section 2 of the guidance links to an algorithm to help you decide whether or not your research is a clinical trial of an investigational medicinal product (CTIMP). Specific advice may be sought by emailing clintrialhelpline@mhra.gov.uk; If the research is a CTIMP, you must select the first option in answer to Question 2 on the project filter.

Devices research

If your research is a study of a medical device, please select the appropriate option on the Project Filter rather than "Other clinical trials or investigations".

Guidance on medical devices research is available on the HRA website at:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/medical-devices-and-software-applications/

Guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

For specific advice on devices research, please contact MHRA Devices at devices.regulatory@mhra.gov.uk .

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Basic science study involving procedures with human participants

This option may involve patients or healthy volunteers as participants, but the study does not affect any clinical care that the participant may be receiving. It is appropriate for scientific investigations involving procedures with participants that are additional to any clinical care, but not studying a novel clinical intervention or involving randomisation between treatment groups or any other change in existing clinical care.

For example, it would be suitable for studies involving:

- Imaging investigations (MRI, ultrasound etc)
- Physical examinations
- Physical tests
- Computer tests
- Filming or photography
- Sample-taking.

Where the study involves taking samples but no other physical intervention or procedure, you may select either this option or *"Research limited to use of tissue, other human biological samples and/or data"*. The set of questions generated in the application form(s) in IRAS will be the same in either case.

Where the study involves questionnaires and interviews but no physical interventions or procedures, it would be more appropriate to select the option *"Research involving questionnaires or interviews for quantitative analysis or mixed quantitative/qualitative methodology"*.

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Study administering questionnaires/interviews for quantitative or mixed quantitative/qualitative analysis

Please select this option if your research:

- Involves no clinical interventions or procedures (otherwise please select one of the clinical research categories);
- Involves administering a questionnaire, or conducting interviews or focus groups with participants; and
- Will use quantitative analysis, or a mix of quantitative and qualitative analysis methods.

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Study involving qualitative methods only

Please select this option if your research:

- Involves no clinical interventions or procedures (otherwise please select one of the clinical research categories)
- Involves no use of human tissue samples or other human biological materials
- Will use only qualitative analysis methods.

If you select this option, questions in IRAS relating to statistical analysis will be disabled.

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Study limited to working with human tissue samples and/or analysis of data

Research in this category is based entirely on the analysis data and/or use of human tissue samples or other human biological material. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to collect samples and seek informed consent where appropriate.

This category applies to *specific research projects* using samples and/or data. Where a favourable ethical opinion is given, this will apply for the duration of this project only. To apply for ethical review of a licensed research tissue bank or a research database, please select the appropriate category.

If you select this option, supplementary questions will appear about the proposed use of data or human tissue samples in your study. The version of the form applicable to your project will depend on your answers to these questions. Tick all options that apply.

Research involving data collection through questionnaires or other intervention with participants should select another option.

The HRA provides a free e-learning module on research involving human tissue, which can be accessed from their website here.

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Study limited to working with data

Research in this category is based entirely on the use of data from patients, service users or other data subjects. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to seek informed consent where appropriate.

This category applies to research involving data relating to the deceased, as well as to living data subjects.

This category applies to **specific research projects** using data to investigate specific research question(s) described in a protocol. Where a favourable ethical opinion is given, this will apply for the duration of this project only.

This category is suitable for specific projects which may be sourcing datasets from a research database for their study. However, if you are a database manager and wish to apply for ethical review of the **research database** itself, including generic approval for the research programme supported by the database, please select the appropriate category within the Project Filter.

If you select this option, a supplementary question will appear about the identifiability of the data to be used in your study. The version of the form applicable to your project will depend on your answer to this question. A simpler version will apply where the research team will only have access to anonymised or effectively pseudonymised (coded) data.

Research involving questionnaires, interviews, focus groups or other intervention with participants should select another option.

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Research tissue bank

Organisations responsible for the management of research tissue banks (RTB) anywhere in the UK may apply for ethical review of their arrangements for collection, storage, use and distribution of tissue.

A "research tissue bank" (or "biobank") is defined by Research Ethics Service Standard Operating Procedures as:

"A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending."

A research tissue bank can store different types of biological material, including DNA, serum, cell

lines and “relevant material”, as defined by the Human Tissue Act 2004.

If your research is a specific research project involving human tissue you should select another option on the Project Filter.

Licensing requirements

Under the Human Tissue Act 2004, RTBs in England, Wales and Northern Ireland storing relevant material for use in as yet unspecified research must obtain a licence from the Human Tissue Authority (HTA).

Applicants for ethical review of RTBs will be expected to provide the REC with a copy of the licence as a condition of ethical approval except where:

- The RTB is established in Scotland (in Scotland there is an accreditation scheme for NHS Research Scotland RTBs).

- The RTB is not storing "relevant material" as defined by the Human Tissue Act 2004 (e.g. it is storing DNA, serum, cell lines).

Detailed guidance about licensing is available on the HTA website.

Application for ethical review is voluntary

There is no formal requirement for RTBs to obtain ethical approval under the Human Tissue Act 2004, under NHS research governance systems or under Governance Arrangements for Research Ethics Committees (GAfREC). Applications for ethical review will therefore be made on a voluntary basis.but ethical approval for an RTB may have benefits by facilitating programmes of research without a need for individual project-based ethical approval.

RECs will normally only review RTBs established by organisations within the UK. However, applications related to non-UK RTBs may be accepted for review where the bank plans to collect tissue/data relating to UK participants.

The REC RTB application form has an option for the applicant to seek generic ethical approval prospectively for a range of research to be carried out by the establishment responsible for the RTB and/or by other researchers to whom tissue is released by the RTB within the conditions of the ethical approval. Such approval may be given for a period of up to five years and will be renewable.

Booking applications

Applications for ethical review of RTBs are booked for review via the online booking service, which is accessed via the E-submission tab of the REC RTB Form.

It is recommended that applicants book to a “flagged REC", which has been assigned to review RTB applications and has received additional training. However, applicants may opt to apply to another REC within their geographical domain if they prefer.

Further guidance

For further guidance refer to:

- FAQs on the Human Tissue Act are available on the Health Research Authority (HRA) website
- Research Ethics Service Standard Operating Procedures at: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/
- The HRA provides a free e-learning module on research involving human tissue, which can be accessed from the HRA website.

NHS/HSC management permission

Under the UK Policy Framework for Health & Social Care Research, there is no requirement for NHS management permission for the establishment of RTBs in the NHS/HSC. Applications through IRAS are not required as all NHS/HSCorganisations are expected to have included management review in the process of establishing the RTB and, where applicable, applying for licensing.

Tissue Collection Centres

Tissue Collection Centres (TCCs) are not research sites for the purposes of the UK Policy Framework for Health and Social Care Research.

NHS/HSC management permission is not required by collaborators at TCCs who provide tissue samples or other biological material and/or data to an RTB under the terms of a supply agreement between the care organisation and the RTB.

RTB managers are advised to provide NHS/HSC R&D offices at all TCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All TCCs should be listed in Part C of the REC application.

NHS/HSC researchers undertaking specific research projects using tissue/data supplied by an RTB must apply for permission to R&D offices at all organisations where the research is conducted,

whether the RTB has ethical approval or not. Where the tissue/data is received in non-identifiable form and the research is covered by the terms of generic ethical approval for the RTB, no further REC application is required but the RTB should list the projects in its annual report to the REC.

If the TCC is storing relevant material as defined by the Human Tissue Act 2004, there are licensing implications to be considered. The TCC will require a HTA research storage licence unless the relevant material is being stored: (i) incidental to transportation' (the timeframe for this is up to one week); or (ii) pending processing to extract DNA or RNA, or other subcellular components that are not relevant material (the timeframe for this is also up to one week).

Further details on these licensing exemptions are given in the HTA's Code of Practice and Standards on Research (Code E).

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Research database

Organisations responsible for the management of research databases anywhere in the UK may apply for ethical review of their arrangements for collection, storage and use of data, including arrangements of release of data to researchers.

A "research database" is defined as:

A collection of data, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

Application for ethical review is voluntary

There is no formal requirement for databases to apply for ethical review under NHS research governance systems or under Governance Arrangements for Research Ethics Committees (GAfREC). Ethical review would only be required by legislation if processing identifiable data without consent. Applications for ethical review will therefore normally be made on a voluntary basis but ethical approval for a research database may have benefits by facilitating programmes of research without a need for individual project-based ethical approval.

The database application form has an option for the applicant to seek generic ethical approval prospectively for a range of research to be carried out by the establishment responsible for the database and/or by other researchers to whom data is released within the conditions of the ethical approval. Such approval may be given for a period of up to 5 years and will be renewable.

Booking applications

Applications for ethical review of research databases are booked for review via the online booking module, which is accessed via the E-submission tab of the REC RDB Form.

It is recommended that applicants book to a "flagged REC", which has been assigned to review RDB applications and has received additional training. However, applicants may opt to apply to another REC within their geographical domain if they prefer.

NHS management permission

Under the UK Policy Framework for Health & Social Care Research, there is no requirement for NHS management permission for the establishment of research databases in the NHS/HSC. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the UK Policy Framework.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval. Where the data is received in non-identifiable form and the research is covered by the terms of generic ethical approval for the database, no further REC application is required but the database should list the project in its annual report to the REC.

Guidance last updated: 19 December 2022

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Other research

Select this option only if your research does not appear to fit any other category.

Selecting this option will generate a comprehensive version of the IRAS dataset, appropriate for example to an interventional clinical trial. You may wish to consider selecting another option to ensure that the dataset omits questions not relevant to your study. Further guidance on the types of study that are appropriate to each of the categories is available by clicking on the information buttons. If you require further advice, please contact the IRAS Queries Line at iras.queries@hra.nhs.uk

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Clinical trials of investigational medicinal products (CTIMPs)

IMPORTANT:

It is no longer possible for CTIMP applications to be made using this part of IRAS. If you have an existing CTIMP project and have not yet submitted your MHRA Medicines, IRAS, REC or GTAC forms (as applicable), you will no longer be able to do so here.

All CTIMPs now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

If you are already preparing a combined review application and your project will involve either ionising radiation or an investigational medical device, please refer to IRAS Help guidance.

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Other research

Select this option only if your research does not appear to fit any other category.

Selecting this option will generate a comprehensive version of the IRAS dataset, appropriate for example to an interventional clinical trial. You may wish to consider selecting another option to ensure that the dataset omits questions not relevant to your study. Further guidance on the types of study that are appropriate to each of the categories is available by clicking on the information buttons. If you require further advice, please contact the IRAS Queries Line at iras.queries@hra.nhs.uk

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Commercial sponsorship or funding

Answer YES if the study is sponsored or funded by the manufacturer of the device or by any other commercial company. This includes support for the study through provision of the device free of charge. It does not include arrangements to share the data from the study with the manufacturer.

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Clinical investigation for UKCA/CE UKNI/CE marking purposes

Select this option where the manufacturer is sponsoring or funding an investigation intended to provide clinical data to support UKCA/CE UKNI/CE marking of the device, or a change to existing UKCA/CE UKNI/CE marking. It may apply to any of the following:

- A non-UKCA/CE UKNI/CE marked medical device;
- A UKCA/CE UKNI/CE marked device which has been modified; or
- A UKCA/CE UKNI/CE marked device, which is being used outside its intended purpose.

If you select this option, IRAS will generate the forms required to notify the MHRA of the investigation and apply for a Notice of No Objection.

The regulations on clinical investigations apply only to general medical devices and active implantable medical devices. For in-vitro diagnostic devices, select the specific option for performance evaluation of IVDDs.

Further guidance is available on the Health Research Authority (HRA) website at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/medical-devices-and-software-applications/

Detailed guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

For specific advice, please contact MHRA Devices at devices.regulatory@mhra.gov.uk.

Pilot of coordinated assessment pathway for clinical investigations of medical devices: the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) are working together to test a coordinated assessment pathway that will streamline the review of clinical investigations of medical devices. To find out more and register your interest visit the MHRA website.

IMPORTANT: **Research involving an in vitro diagnostic device (IVD):**

Currently, different EU regulation applies to studies that involve a performance evaluation of an IVD taking place in Northern Ireland compared to the rest of the UK.

If your research will be a performance evaluation of an in vitro diagnostic device AND will be taking place in Northern Ireland you should refer to our guidance for more information on how to complete your application.

If, after consulting our guidance, you have determined that a full application is required to MHRA for your IVD research taking place in Northern Ireland - **select this option to correctly generate the required fields**. Further instructions on how to apply can be found on IRAS Help.

Guidance last updated: 22 March 2024

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Clinical trial of a drug/device combination (IMP/Device Trial)

IMPORTANT:

It is no longer possible for a new IMP/Device trial application to be made using this part of IRAS. If you have an existing IMP/Device project and have not yet submitted your MHRA Medicines, IRAS or REC forms (as applicable) you should contact cwow@hra.nhs.uk.

All new IMP/Device trial applications should now follow the process outlined in IRAS Help.

If you are completing an existing IMP/Device trial application using this part of IRAS, the guidance below can still be used to help you to complete your application. Applicants with an existing IMP/Device project should ensure their application is submitted by 28 February 2022.

This option only applies where the trial involves the use of ***both*** an investigational medicinal product ***and*** an investigational medical device (either a non-UKCA/CE UKNI/CE marked device or a device which has been modified or is being used for a purpose not covered by the UKCA/CE UKNI/CE mark).

In these circumstances, the trial would exceptionally require ***both***:

- Notice of No Objection under the UK Medical Devices Regulations 2002 (for studies involving Great Britain only), or authorisation under the EU Medical Devices Regulation 2017/745 (for studies involving Northern Ireland) ***and***

- Clinical trial authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004.

This option should also be used for studies involving an investigational medicinal product ***and*** a CE marked medical device (Post Market Study of the medical device that also involve procedures additional to the normal conditions of use of the device, that are also invasive or burdensome) and are conducted in Northern Ireland.

Applicants are advised to seek expert advice from either branch of MHRA on the regulatory requirements for combined drug/device trials. Contact either of the following:

- Clinical Trials Helpline (for medicinal trials) at clintrialhelpline@mhra.gov.uk or 020 3080 6456

- MHRA Devices (for devices investigations), at devices.regulatory@mhra.gov.uk.

Where MHRA advise that the trial will be regulated under only the Medicines or Devices Regulations, please untick the combined drug/device option and proceed as follows:

- If regulated only as a medicinal trial, select "Clinical trial of an investigational medicinal product".

- If regulated only as a devices investigation, select "Clinical investigation or other study of a medical device".

The HRA provides a free e-learning module on regulations and considerations for clinical investigations or other research studies of medical devices across the UK which can be accessed from their website here.

Guidance last updated: 04 January 2022

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Post-market clinical study involving a change to standard care or randomisation between groups

Select this option where the study involves:

- UKCA/CE UKNI/CE marked device(s) which have not been modified and are being used in accordance with their intended purpose; and

- Change to standard care for patients (at any site), or randomisation between groups.

"Change to standard care" means that there could be a change to the patient's treatment if they opt to take part in the study, compared to the treatment normally provided outside the study.

For studies involving Northern Ireland only – this option should only be used for studies involving CE marked medical devices that also involve procedures additional to the normal conditions of use of the device, that are also invasive or burdensome (Post Market Studies). A notification must be submitted to MHRA for such post market studies. Ensure the Medicines and Healthcare products Regulatory Agency (MHRA) Devices Division is selected under Question 4 of the IRAS Project Filter.

Where use of the device is already part of current clinical practice at all participating sites, or is to be adopted as standard clinical practice prior to or alongside the start of the study, the option "Registry of a UKCA/CE UKNI/CE marked device in clinical use" may be selected instead.

Selection of this option produces a version of the integrated dataset in Part A of IRAS appropriate to a clinical trial. Part B Section 2 of IRAS will also be enabled to provide details of the device under study. Depending on the procedures involved in the study, additional sections of Part B may be enabled.

Guidance last updated: 25 May 2021

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Registry of a UKCA/NE UKNI/CE marked device in clinical use, involving no change to standard care or randomisation

Select this option where the study involves:

- UKCA/CE UKNI/CE marked device(s) which have not been modified and are being used in accordance with their intended purpose; and
- No change to standard care for patients (at any site), or randomisation between groups.

"Change to standard care" means that there could be a change to the patient's treatment if they opt to take part in the study, compared to the treatment normally provided outside the study.

This option is appropriate where use of the device is already part of standard clinical practice at all participating sites, or is to be adopted as standard clinical practice prior to or alongside the start of the study.

Selection of this option produces a shorter version of the integrated dataset in Part A of IRAS. Part B Section 2 of IRAS will be enabled to provide details of the device under study. Depending on the procedures involved in the study, additional sections of Part B may be enabled.

Post Market Surveillance – review requirements

It is only necessary to apply for ethical review by a NHS REC and management permission for research from NHS R&D offices where a project is considered to be *research*.

It is the sponsor's responsibility to determine whether a project should be reviewed as research, in consultation with the host organisations for the project as necessary. Where advice is required, please seek advice initially from the R&D office at the lead site. Further advice may be sought from the Health Research Authority (HRA) Queries Line by emailing queries@hra.nhs.uk, enclosing a summary of the protocol.

Post Market Surveillance (PMS) studies of UKCA/CE UKNI/CE marked devices may be classified as *service evaluation*, not requiring ethical review or management permission from NHS R&D offices, where all the following criteria are met:
(i) The product is used unmodified and within its intended purpose;
(ii) The assignment of any patient involved in the study to a particular therapeutic strategy or diagnostic procedure is not decided in advance by a protocol but falls within current clinical practice;
(iii) The decision to use the product is clearly separated from the decision to include the patient in the study;
(iv) No diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of current clinical practice; and
(v) Epidemiological methods are to be used for the analysis of the data arising from the study.

If the study does not meet all of these criteria, it should be regarded as research. In particular, any case series study involving additional research procedures (e.g. scans, questionnaires) or additional clinical monitoring should be regarded as research and will require ethical review and R&D approval if conducted within the NHS.

Guidance last updated: 22 December 2020

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Performance evaluation of an In Vitro Diagnostic Device (PEIVDD)

IMPORTANT: Research involving an in vitro diagnostic device (IVD): Currently, different EU regulation applies to studies that involve a performance evaluation of an IVD taking place in Northern Ireland compared to the rest of the UK.

If your research will be a performance evaluation of an in vitro diagnostic device (PEIVDD) (as outlined below) AND will be taking place in Northern Ireland you should refer to our guidance for more information on how to complete your application.

This option should be selected for a PEIVDD. This means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises.

PEIVDDs do not require a Notice of No Objection from the MHRA. Applicants are not required to apply to MHRA Devices using IRAS.

However, notification is required under the In Vitro Diagnostic Devices Directive as implemented by and the UK Medical Devices Regulations 2002 (as amended). Guidance is available on the MHRA website at: https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device#in-vitro-diagnostic-medical-devices-ivds

Selection of this option produces a shorter version of the integrated dataset in Part A of IRAS. Part B Section 2 of IRAS will be enabled to provide details of the device under study. Depending on the procedures involved in the study, for example use of human tissue samples, additional sections of Part B may be enabled.

Where PEIVDDs are conducted at NHS/HSC sites, ethical review should be sought from a NHS Research Ethics Committee and permission obtained to conduct the research at NHS/HSC sites. If the PEIVDD does not involve any NHS/HSC sites, the study does not need to be submitted for REC review unless there is another legal or policy requirement for REC review under the Governance Arrangements for Research Ethics Committees (GAfREC).

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Clinical study of a non-UKCA/CE UKNI/CE marked device where commercialisation is intended

This option should be selected where, although not commercially sponsored or funded, the study is intended to provide clinical data to support potential commercial development of the device. Such studies are regulated under the UK Medical Devices Regulations 2002 (as amended) (for studies involving Great Britain only) and require a Notice of No Objection from the MHRA, or authorisation under the EU Medical Devices Regulation 2017/745 (for studies involving Northern Ireland).

For example, this option should be selected where a university or healthcare organisation has developed a novel device in-house and is collaborating with, or plans to collaborate with, a commercial company with the intention of manufacturing and marketing the product commercially.

This option also applies where the study relates to an existing UKCA/CE UKNI/CE marked device, which has been modified or is being used outside its intended purpose, and the manufacturer intends to use clinical data from the study to support a change to UKCA/CE UKNI/CE marking.

Selection of this option produces a version of the integrated dataset in Part A appropriate to a clinical trial. Part B Section 2 of IRAS will also be enabled to provide details of the device under study. Depending on the procedures involved in the study, additional sections of Part B may be enabled.

If you select this option, IRAS will generate the forms required to notify the MHRA of a clinical investigation and apply for a Notice of No Objection.

Detailed guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

For specific advice, please contact MHRA Devices (see contact details on the web page above).

Pilot of coordinated assessment pathway for clinical investigations of medical devices:

the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) are working together to test a coordinated assessment pathway that will streamline the review of clinical investigations of medical devices. To find out more and register your interest visit the MHRA website.

Guidance last updated: 30 July 2021

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Clinical study of a non-UKCA/CE UKNI/CE marked device where commercialisation is not intended

This option should be selected for non-commercial clinical studies of novel devices, developed for use within a single entity, with no plans for commercial development of the product.

For example, this option should be selected where a university or healthcare organisation has developed a novel device solely for its own use, and there is no intention to collaborate with a commercial company to market the product commercially.

This option also applies where the study relates to an existing UKCA/CE UKNI/CE marked device, which has been modified by the host organisation, and there are no plans for the manufacturer to use clinical data from the study to support a change to UKCA/CE UKNI/CE marking of the product.

Collaboration with another body in the design and manufacturing of the device does not exclude selection of this option, provided that it will be used within a single entity and commercialisation is not intended.

Selection of this option produces a version of the integrated dataset in Part A appropriate to a clinical trial.

Part B Section 2 of IRAS will also be enabled to provide details of the device under study, and includes a requirement for an additional declaration from the head of clinical engineering (or equivalent) at the institution. In the absence of regulatory review by the MHRA, this declaration provides review bodies with assurance that the device has been manufactured and tested to comply with relevant quality standards, prior to clinical testing.

Depending on the procedures involved in the study, additional sections of Part B may be enabled.

Selection of this option does not generate the forms required to notify the MHRA of a clinical investigation and apply for a Notice of No Objection, as this is not required for a study of this type.

Further guidance is available on the Health Research Authority (HRA) website at:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/medical-devices-and-software-applications/

Detailed guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

For specific advice, please contact MHRA Devices (see contact details on the web page above). If after further consideration and consultation with MHRA it is established that notification of the MHRA is required, please select instead the option for a clinical study where commercialisation is intended.

Guidance last updated: 22 December 2020

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Clinical study of UKCA/CE UKNI/CE marked device for an off-label indication

This option should be selected for non-commercial studies of UKCA/CE UKNI/CE marked devices, where the product is being used outside the intended purpose specified in the UKCA/CE UKNI/CE mark but there are no plans for the manufacturer to use clinical data from the study to support a change to UKCA/CE UKNI/CE marking of the product.

Selection of this option produces a version of the integrated dataset in Part A appropriate to a clinical trial. Part B Section 2 of IRAS will also be enabled to provide details of the device under study. Depending on the procedures involved in the study, additional sections of Part B may be enabled.

Selection of this option does not generate the forms required to notify the MHRA of a clinical investigation and apply for a Notice of No Objection, as this is not required for a study of this type.

Further guidance is available on the Health Research Authority website at:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/medical-

devices-and-software-applications/

Detailed guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

For specific advice on the regulation of devices, please contact MHRA Devices (see contact details on the web page above).

If after further consideration and consultation with MHRA it is established that notification of the MHRA is required, please select instead the option for a clinical study where commercialisation is intended.

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Clinical study of UKCA/CE UKNI/CE marked device(s) for a labelled indication, involving a change to standard care or randomisation between groups

This option should be selected for non-commercial studies of UKCA/CE UKNI/CE marked devices, where the product has not been modified and is being used within the intended purpose specified in the UKCA/CE UKNI/CE mark, but the study involves a change to standard care or randomisation between groups.

For example, this option would be appropriate for a clinician-led trial to compare the safety and efficacy of devices already on the market for the same indication.

"Change to standard care" means that there could be a change to the patient's treatment if they opt to take part in the study, compared to the treatment normally provided outside the study.

Selection of this option in the project filter questions will produce a version of the integrated dataset in Part A appropriate to a clinical trial. Part B Section 2 of IRAS will also be enabled to provide details of the device under study. Depending on the procedures involved in the study, additional sections of Part B may be enabled.

Where use of the device is already part of current clinical practice at all participating sites, or is to be adopted as standard clinical practice prior to or alongside the start of the study, the option for a study in a labelled indication involving no change to standard care or randomisation between groups may be selected instead. This would produce a shorter version of Part A.

Research involving Northern Ireland

Please note that from 26 May 2021 Studies taking place in Northern Ireland should select this option for studies involving CE marked devices that also involve procedures additional to the normal conditions of use of the device, that are also invasive or burdensome (Post Market Studies).

A notification must be submitted to MHRA for such post market studies. Ensure the Medicines and Healthcare products Regulatory Agency (MHRA) Devices Form is selected under Question 4 of the IRAS Project Filter.

Notification to the MHRA is *not* required for studies of UKCA/CE UKNI/CE marked devices for labelled indications unless the study is conducted in Northern Ireland and involves additional invasive and burdensome procedures.

Further guidance

Further guidance is available on the Health Research Authority website at:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/medical-devices-and-software-applications/

Detailed guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

Guidance last updated: 26 May 2021

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Clinical study of UKCA/CE UKNI/CE marked device(s) for a labelled indication, involving no change to standard care or randomisation between groups

This option should be selected for non-commercial studies of UKCA/CE UKNI/CE marked devices, where the product has not been modified and is being used within the intended purpose specified in the UKCA/CE UKNI/CE mark, with no change to standard care of patients or randomisation between groups.

For example, this option would be appropriate for a clinician-led case series study to evaluate

clinical outcomes from a device already in use at all participating sites.

"Change to standard care" means that there could be a change to the patient's treatment if they opt to take part in the study, compared to the treatment normally provided outside the study.

Selection of this option does not exclude additional research procedures as part of the protocol, e.g. additional scans, questionnaires, sample or data collection, provided that patient treatment is not altered.

This option will produce a shorter version of the integrated dataset in Part A of IRAS. Part B Section 2 of IRAS will be enabled to provide details of the device under study. Depending on the procedures involved in the study, additional sections of Part B may be enabled.

Further guidance is available on the Health Research Authority website at:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/medical-devices-and-software-applications/

Detailed guidance on requirements for approval of clinical investigations by MHRA Devices is available on the MHRA website:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

Notification to the MHRA is ***not*** required for studies of UKCA/CE UKNI/CE marked devices for labelled indications unless the study is conducted in Northern Ireland and involves additional invasive and burdensome procedures, in which case **"Clinical study of UKCA/CE UKNI/CE marked device(s) for a labelled indication, involving a change to standard care or randomisation between groups"** should be selected instead.

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Pre-clinical device development or performance testing

Select this option where applications are required for non-clinical research undertaken as part of a device development programme, not involving use of the device in the course of patient care.

It is recommended that researchers seek advice from their NHS R&D office on whether applications are required for research of this type.

Ethical review by a REC is not required for bench research simply because it takes place on NHS premises or involves NHS facilities and resources. However, ethical review could be required

where a project involves, e.g. the collection of tissue samples from NHS patients or use of non-consented stored samples in testing a device.

The R&D office can also advise on whether application is required for management permission to undertake research. There may be instances where, although REC review is not required, R&D review is still needed to ensure appropriate use of NHS resources and minimisation of any risks to the organisation or the researchers themselves.

Selection of this option will produce a significantly reduced version of the integrated dataset in Part A of IRAS, appropriate to a non-clinical study.

Part B Section 2 of IRAS will be enabled to provide details of the device under study. For this type of study, Part B Section 2 includes a requirement for an additional declaration from the head of clinical engineering (or equivalent) at the institution. This is intended to provide review bodies with assurance that the device is being manufactured and tested in accordance with relevant quality standards.

Depending on the procedures involved in the study, additional sections of Part B may be enabled, for example to provide information about the use of human tissue samples.

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Trials subject to advice from EAG/CHM

Introduction

For certain types of clinical trial the MHRA will seek advice from the Expert Advisory Group on Clinical Trials (EAG) and the Commission on Human Medicine (CHM) before giving approval. Examples of trials were expert advice may be needed can be found on the MHRA website at: https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk.

Applicants should indicate in answer to Question 2a whether the proposed trial falls within the scope of the expert advice arrangements.

Sponsors are requested to make contact with the Agency before making the application for Clinical Trial Authorisation (CTA) for such trials and to make available a data package allowing that advice to be obtained. The normal CTA application timeline will follow receipt of a valid application.

Scope of the EAG/CHM arrangements

The decision to refer applications for expert advice will be based on assessment of risk factors and the proposed mitigation strategy. Areas for consideration when determining risk factors include mode of action, nature of the target and the relevance of animal species and models.

First in human (FIH) trials with novel compounds

The arrangements apply to certain types of First in Human (FIH) trial with novel compounds.

Sponsors of all FIH trials should take account of the Guideline on Strategies to Identify and Mitigate Risks for First-in-Human Clinical Trials with Investigatival Medicinal Products at https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf.

Implications for REC applications

Applicants should indicate in answer to Question 2a whether the proposed trial falls within the scope of the EAG/CHM arrangements.

If so, please explain the current status of the application for CTA in answer to Question A55 in IRAS. Further guidance is available from the information button next to this question. A copy of any relevant correspondence with MHRA should be enclosed with the REC application.

The sponsor is responsible for ensuring that the REC is kept informed about the progress of the CTA application and any changes made to the trial as a result of the expert advice from EAG/CHM. The REC should be fully informed about this either as part of the initial application or through further information provided in the course of the ethical review.

Sequential or parallel processing?

Sponsors may opt to apply either sequentially or in parallel to the MHRA and the REC.

This decision may be influenced by a number of considerations. A sequential process may be preferable where, despite pre-submission advice from MHRA, factors such as the novelty of the compound including its mode of action and target, the relevance of animal models and the completeness of the data package available may result in protocol changes following EAG/CHM review. A sequential process would allow the ethics committee to receive the final version of the protocol and be fully informed about the outcome of the CTA application when undertaking its review.

However, in other cases the sponsor may be confident that the protocol is unlikely to change and may wish to apply in parallel.

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Gene therapy medicinal products

Gene therapy medicinal products are defined in Part IV of Directive 2003/63/EC (amending Directive 2001/83/EC) as follows:

> *"... [a] gene therapy medicinal product means a product obtained through a set of manufacturing processes aimed at the transfer, to be performed either in vivo or ex vivo, of a prophylactic, diagnostic or therapeutic gene (i.e. a piece of nucleic acid), to human/animal cells and its subsequent expression in vivo. The gene transfer involves an expression system contained in a delivery system known as a vector, which can be of viral, as well as non-viral origin. The vector can also be included in a human or animal cell."*

For more information please refer to: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/gene-therapy-advisory-committee/ .

If you select Yes in answer to this question, the application for ethical review must be submitted to GTAC.

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Ionising radiation

You should answer "Yes" to this question if the research protocol includes any research exposure involving ionising radiation as defined in the Ionising Radiation (Medical Exposure) Regulations ("IRMER"). In considering your response to this question you should be clear whether procedures will involve ionising or non-ionising radiation (see guidance below) and whether any ionising radiation is a research exposure (guidance on whether ionising radiation exposures should be defined as research exposures is provided in IRAS Help).

For all studies where the answer to this question is "Yes", Part B Section 3 of IRAS will be enabled and should be completed with input from a lead Medical Physics Expert (MPE) and lead Clinical Radiation Expert (CRE). Further guidance is provided in this section of IRAS.

If the research involves (or might involve) ionising radiation at any stage, you should seek early advice from an MPE on completion of Part B Section 3 and compliance with IRMER.

Ionising and non-ionising radiation procedures

Examples of procedures involving ionising radiation include:

- X-ray
- Computed tomography (CT) scan
- Angiography
- Mammography
- Fluoroscopy
- Endoscopic retrograde cholangio pancreatography (ERCP)
- Intravenous Urogram (IU)
- Dual energy x-ray absorptiometry (DEXA/DXA)
- Radiotherapy, including, but not limited to:
    - 3D conformal radiotherapy (3DCRT)
    - 4D conformal radiotherapy (4DCRT)
    - Intensity-modulated radiotherapy (IMRT)
    - Imaging-guided radiotherapy (IGRT)
    - Stereotactic body radiotherapy (SBRT)

Examples of procedures involving non-ionising radiation include:

- Magnetic Resonance Imaging (MRI)
- Optical Coherence Tomography (OCT)
- Ultrasound
- Echocardiogram (ECHO)

Note: non-ionising radiation procedures do not need to be declared in Part B Section 3. If your research only involves non-ionising radiation procedures then you should select "no" to this question.

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You should answer “Yes” to this question if the research protocol includes any research exposure involving the administration of radioactive substances.

For all studies where the answer to this question is “Yes”, the application to ARSAC will be selected at filter question 4 and the ARSAC Preliminary Research Assessment (PRA) form will be automatically generated as a project form. Note that the fields in the PRA form are populated from the application for ethical review / integrated dataset. If any fields are blank, please check your application for ethical review or integrated dataset for completeness.

Examples of procedures involving the administration of radioactive substances include:

- Bone scan – also known as scintigram, skeletal scintigraphy or nuclear medicine bone scans
- Glomerular filtration rate (GFR) – not to be confused with the e-GFR which does not use

radiation at all
- Heliobacter pylori urea breath test
- Internal radiotherapy / brachytherapy
- MIBG (metaiodobenzylguanidine) scan
- Multi-gated acquisition (MUGA) scan
- Positron emission tomography (PET) scans
- Red cell mas and plasma volume measurement
- SeHCAT test
- Single photon emission CT (SPECT) scans
- Thyroid uptake measurement

The ARSAC Notes for Guidance give a more complete list of radioactive substances and procedures which are administered in the UK.

Diagnostic X-rays, CT scans and DXA do not usually involve the administration of radioactive materials. However, radiation procedures sometimes involve the administration of a contrast agent. Most of the time the contrast agent will be non-ionising.

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New human tissue samples (or other human biological samples)

Please answer Yes if the research will involve collecting samples prospectively from participants primarily for research purposes.

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Existing human tissue samples (or other human biological samples)

Please answer Yes if the research will involve the use of residual material left over from routine clinical or diagnostic procedures, or existing stored samples from an archived collection or tissue bank.

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Ionising radiation

You should answer “Yes” to this question if the research protocol includes any research exposure involving ionising radiation as defined in the Ionising Radiation (Medical Exposure) Regulations ("IRMER"). In considering your response to this question you should be clear whether procedures will involve ionising or non-ionising radiation (see guidance below) and whether any ionising radiation is a research exposure (guidance on whether ionising radiation exposures should be defined as research exposures is provided in IRAS Help).

For all studies where the answer to this question is “Yes”, Part B Section 3 of IRAS will be enabled and should be completed with input from a lead Medical Physics Expert (MPE) and lead Clinical Radiation Expert (CRE). Further guidance is provided in this section of IRAS.

If the research involves (or might involve) ionising radiation at any stage, you should seek early advice from an MPE on completion of Part B Section 3 and compliance with IRMER.

Ionising and non-ionising radiation procedures

Examples of procedures involving ionising radiation include:

- X-ray
- Computed tomography (CT) scan
- Angiography
- Mammography
- Fluoroscopy
- Endoscopic retrograde cholangio pancreatography (ERCP)
- Intravenous Urogram (IU)
- Dual energy x-ray absorptiometry (DEXA/DXA)
- Radiotherapy, including, but not limited to:
    - 3D conformal radiotherapy (3DCRT)
    - 4D conformal radiotherapy (4DCRT)
    - Intensity-modulated radiotherapy (IMRT)
    - Imaging-guided radiotherapy (IGRT)
    - Stereotactic body radiotherapy (SBRT)

Examples of procedures involving non-ionising radiation include:

- Magnetic Resonance Imaging (MRI)
- Optical Coherence Tomography (OCT)
- Ultrasound
- Echocardiogram (ECHO)

Note: non-ionising radiation procedures do not need to be declared in Part B Section 3. If your research only involves non-ionising radiation procedures then you should select "no" to this question.

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You should answer "Yes" to this question if the research protocol includes any research exposure involving the administration of radioactive substances.

For all studies where the answer to this question is "Yes", the application to ARSAC will be selected at filter question 4 and the ARSAC Preliminary Research Assessment (PRA) form will be automatically generated as a project form. Note that the fields in the PRA form are populated from the application for ethical review / integrated dataset. If any fields are blank, please check your application for ethical review or integrated dataset for completeness.

Examples of procedures involving the administration of radioactive substances include:

- Bone scan – also known as scintigram, skeletal scintigraphy or nuclear medicine bone scans
- Glomerular filtration rate (GFR) – not to be confused with the e-GFR which does not use radiation at all
- Heliobacter pylori urea breath test
- Internal radiotherapy / brachytherapy
- MIBG (metaiodobenzylguanidine) scan
- Multi-gated acquisition (MUGA) scan
- Positron emission tomography (PET) scans
- Red cell mas and plasma volume measurement
- SeHCAT test
- Single photon emission CT (SPECT) scans
- Thyroid uptake measurement

The ARSAC Notes for Guidance give a more complete list of radioactive substances and procedures which are administered in the UK.

Diagnostic X-rays, CT scans and DXA do not usually involve the administration of radioactive materials. However, radiation procedures sometimes involve the administration of a contrast agent. Most of the time the contrast agent will be non-ionising.

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Research taking new human tissue samples

This option should be selected for research in which samples are collected prospectively from

participants primarily for research purposes.

The HRA provides a free e-learning module on research involving human tissue, which can be accessed from their website here.

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Research involving surplus or existing samples identifiable to the researcher

Select this option for research using residual tissue left over from routine clinical or diagnostic procedures or using existing samples from an archived collection or tissue bank, where it is likely that the researcher will be able to identify the donors.

The HRA provides a free e-learning module on research involving human tissue, which can be accessed from their website here.

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Research involving surplus or existing samples not identifiable to the researcher

Select this option for research using residual tissue left over from routine clinical or diagnostic procedures using existing samples from an archived collection or tissue bank, where ***all*** the samples will be anonymised or pseudonymised and there is no possibility of the researcher being able to identify any donor.

The HRA provides a free e-learning module on research involving human tissue, which can be accessed from their website here.

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Research involving identifiable data

This option should be selected for research:

- Using non-anonymised patient or service user data from databases or records

- Observing treatment or care with *no intervention*.

Research involving data collection through questionnaires or other intervention with participants should select another option.

Answer No if your research will *only* use non-identifiable data, i.e. data that are "anonymised" or "pseudonymised" at the point of access by researchers.

Anonymised data The Information Commissioners Office (ICO) refers to anonymised information as "information from which no individual can be identified". Refer to the ICO website for more information.

"Pseudonymised data The ICO describes the process of pseudonymisation as distinguishing individuals in a dataset by using a unique identifier which does not reveal their "real world" identity.

Tissue/data supplied by approved tissue banks and databases

NHS researchers undertaking specific research projects using tissue/data supplied by a Research Tissue Bank or Research Database must still apply for permission to R&D offices at all organisations where the research is conducted, whether or not the bank/database has ethical approval. Where the tissue/data is received in non-identifiable form and the research is covered by the terms of generic ethical approval, no further REC application is required but the bank/database should list the project in its annual report to the REC.

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Research involving identifiable data

This option should be selected for research:

- Using non-anonymised patient or service user data from databases or records

- Observing treatment or care with *no intervention*.

Research involving data collection through questionnaires or other intervention with participants should select another option.

Answer No if your research will *only* use non-identifiable data, i.e. data that are "anonymised" or "pseudonymised" at the point of access by researchers.

Anonymised data The Information Commissioners Office (ICO) refers to anonymised information as "information from which no individual can be identified". Refer to the ICO website for more

information.

"Pseudonymised data The ICO describes the process of pseudonymisation as distinguishing individuals in a dataset by using a unique identifier which does not reveal their "real world" identity.

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Countries of the UK

You are expected to tick at least one check box.

Please tick all the countries in the UK where you expect research sites will be located. In Part C of the application you should enter information about the research sites, which corresponds to the countries you have selected in the project filter.

Please do not select a country if there is no plan to include research site(s) in that country.

Research sites

A research site is defined as the single organisation responsible for conducting the research at a particular locality.

The *research site* is not necessarily the *location* where research activities will actually take place. For example, in a research project by practice nurses from GP practices, interviews with participants may take place in the participant's home, but the research site would be the GP practice, because the GP practice would be responsible for the research activity.

Organisations where clinicians or clinical units refer potential participants to the research team for assessment and possible recruitment are not considered to be research sites.

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Lead R&D Office

The lead NHS R&D contact may be the R&D contact for:

- The Chief Investigator"s employing NHS organisation
- A partner NHS organisation of the university employing the Chief Investigator
- A main NHS collaborator

The lead R&D office should be contacted at the earliest possible stage to advise and support the research through the review process.

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Countries of the UK

- In Question 3 please indicate in which country the research tissue bank is physically located.
- In Question 3a please tick all the countries where centres will be providing tissue and data to the research tissue bank.

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Countries of the UK

- In Question 3a please indicate in which country the research database is physically located.
- In Question 3b please tick all the countries where centres will be providing data to the research database.

Confidentiality Advisory Group (CAG)

- If the database will be processing identifiable patient information relating to people in England and Wales without explicit consent, application may need to be made to the CAG for

approval.

- The remit of CAG covers data about patients living in or receiving care or treatment in England and Wales, whether it is processed in England and Wales or in other countries. Where CAG approves an exemption under Section 251 of the NHS Act 2006, this lifts the common law duty of confidentiality and provides protection to organisations in England and Wales owing that duty.

- Detailed guidance about CAG applications is available next to the CAG option in Question 4.

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IRAS Form

What is the IRAS Form?
From June 2017 all project-based research conducted in or through the NHS/HSC in England, Northern Ireland, Scotland and/or Wales use the 'IRAS Form' to seek:

- HRA and Health and Care Research Wales (HCRW) Approval for research led from England or Wales.
- NHS/HSC R&D Permission and NHS REC review (where required) for research led from Northern Ireland or Scotland.

The IRAS Form should not be selected if your project is not conducted in or through the NHS/HSC. In these circumstances you should select the relevant alternative application form(s) at filter question 4. Please refer to the question specific guidance to assist your selection.

Where projects were created in IRAS prior to June 2017 and separate NHS R&D and/or NHS REC applications have been created then you should continue using these separate applications. You do not need to change your application form type to the IRAS Form.

Further information is set out below.

Research led from England or Wales: HRA and HCRW Approval

What is HRA and HCRW Approval?
HRA and HCRW Approval is the process for the NHS in England and Wales that comprises a review by a NHS Research Ethics Committee (REC), where required, as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA and HCRW staff. It replaces the need for NHS permission by each participating organisation in England and Wales.

Which studies should apply for HRA and HCRW Approval?
You should apply for HRA and HCRW Approval if:

- The lead NHS R&D Office for your project is in England or Wales; and
- Your research is described by any of the IRAS filter question 2 categories (except those for "Research Tissue Bank" and "Research Database").

To apply for HRA and HCRW Approval you should select the option for "IRAS Form" at project filter question 4. Before preparing and submitting your application please ensure that you refer to the guidance for applicants.

While a single IRAS Form is used, different routes of submission apply depending on the location of the lead site and whether REC review is being sought. Please refer to the E-submission/Submission tabs for the IRAS Form.

Research led from Northern Ireland or Scotland: NHS/HSC Management Permission and Research Ethics Committee (REC) review, where appropriate

Project-based research conducted in, or through, the NHS/HSC and led from Northern Ireland or Scotland use the IRAS Form to apply for:

- NHS/HSC Management Permission
- NHS/HSC Research Ethics Committee (REC) review, if required

As the IRAS Form combines the datasets for the above reviews the same single IRAS Form is submitted for both NHS/HSC management permission and ethical review.
IMPORTANT: While a single IRAS Form is used, different routes of submission apply. Please refer to the E-submission/Submission tabs for the IRAS Form.
More information about routes for seeking NHS/HSC management permission is provided at: https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx

Site-level information for participating NHS/HSC organisations
This is dependent on the location of the participating site(s). Please refer to the guidance for more information.

Projects created prior to June 2017
If you created your project in IRAS prior to June 2017 and used separate NHS REC and/or NHS R&D Form(s) then you should continue with these selections and not change to the IRAS Form.

Clinical Trials of Investigational Medicinal Products (CTIMPs) and Combined trials of an investigational medicinal product and an investigational medical device (IMP/Device

trials)

It is no longer possible for CTIMP or IMP/Device trial applications to be made using this part of IRAS. If you have an existing CTIMP or IMP/Device trial project and have not yet submitted your IRAS form, you will no longer be able to do so here.

All CTIMPs and IMP/Device trials now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

If your combined review application will involve either ionising radiation or an investigational medical device, please refer to IRAS Help guidance.

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Application for NHS/HSC management permission

Researchers wishing to conduct research in the NHS (or Health and Social Care in Northern Ireland) must obtain NHS or HSC management permission (also referred to as R&D approval) for each NHS/HSC research site.

Where the research site is a primary care site, e.g. GP practice, the host organisation is the Primary Care Trust (England), Health Board (Scotland), Local Health Board (Wales) or primary care site (Northern Ireland). For other NHS research sites the host organisation is the NHS Trust (England and Wales), Health Board (Scotland) or Health and Social Care Trust (Northern Ireland). Permission to conduct the research will be confirmed by the R&D office to the PI directly

Chief Investigators are responsible for transferring SSI Forms to each Principal Investigator (PI) for completion. Each PI should also be provided with the R&D Form and the full set of documents in the R&D Form checklist.

The process for applying for NHS/ HSC permission varies across the UK. The appropriate instructions for the CI are provided in the submission tab for the R&D Form, and the content of the tab is determined by the location of the lead R&D office as indicated in the project filter. The appropriate instructions for each PI are provided in the submission tab for the SSI Form, and the content of the tab is determined by the location of the lead R&D office selected by the CI and the location of the research site as indicated in the SSI Form.

Further guidance on applying for NHS/HSC management permission is available on the website of the NHS R&D Forum at http://www.rdforum.nhs.uk/. Contact details for R&D offices can be obtained via the links at http://www.rdforum.nhs.uk/content/useful-links/contact-details/ .

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Application to the Social Care Research Ethics Committee

The Research Ethics Committees (RECs) flagged for Social Care in England generally expect to review the following types of social care research:

1. Social care research funded by the Department of Health and Social Care (England) involving adult social care service users as participants.
2. Social care research that involves adults lacking capacity in England and Wales and requires approval under the Mental Capacity Act 2005.
3. Social care research where investigators do not have access to other ethics review systems. This could include service user-led research.
4. Studies of integrated services (health and social care).
5. Intergenerational studies in social care, where both adults and children, or families, are research participants.

The Social Care REC does not consider any research involving clinical interventions. Such research should be reviewed by another appropriate REC within the UK Health Departments' Research Ethics Service.

Social Care applications are expected to fall into one of the categories below:

- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with data (specific project only)
- Research database

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Application to Research Ethics Committee

Detailed guidance on the requirements for ethical approval by Research Ethics Committees within the UK Health Departments' Research Ethics Service is available on the Health Research Authority (HRA) website at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/

On this web page you will find a detailed algorithm, designed to assist researchers, research sponsors and R&D offices in determining whether REC review is required, either under any applicable legislation or under the policy of the UK Health Departments.

For guidance on applying to RECs please refer to: https://www.myresearchproject.org.uk/help/hlpethicalreview.aspx

Clinical Trials of Investigational Medicinal Products (CTIMPs) and Combined trials of an investigational medicinal product and an investigational medical device (IMP/Device trials)

It is no longer possible for CTIMP or IMP/Device trial applications to be made using this part of IRAS. If you have an existing CTIMP or IMP/Device trial project and have not yet submitted your REC Form, you will no longer be able to do so here.

All CTIMPs and IMP/Device trials now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

If your combined review application will involve either ionising radiation or an investigational medical device, please refer to IRAS Help guidance.

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Applying for clinical trial authorisation

Clinical Trials of Investigational Medicinal Products (CTIMPs) and Combined trials of an investigational medicinal product and an investigational medical device (IMP/Device trials).

It is no longer possible for CTIMP or IMP/Device trial applications to be made using this part of IRAS. If you have an existing CTIMP or IMP/Device trial project and have not yet submitted your MHRA Medicines Form, you will no longer be able to do so here.

All CTIMPs and IMP/Device trials now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

If your combined review application will involve either ionising radiation or an investigational

medical device, please refer to IRAS Help guidance.

Clinical trial authorisation (CTA) from the licensing authority (acting by MHRA Medicines) is required for any clinical trial of an investigational medicinal product (CTIMP) to be conducted in the UK.

Please refer to the QSG on the CTIMP option in Question 2 for guidance on how to determine whether your project is a CTIMP.

Applications to MHRA may be made through IRAS. For further details see the guidance on applying to the MHRA .

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Application to MHRA Devices

This option should be selected for a clinical investigation of a medical device undertaken by the manufacturer for UKCA/CE UKNI/CE marking purposes. This will be either an investigation of a non-UKCA/CE UKNI/CE marked product, or an investigation of a UKCA/CE UKNI/CE marked product that has been modified or is to be used outside its intended purpose. Notice of No Objection for such investigations must be obtained from MHRA Devices prior to starting the study. The forms required to apply to MHRA can be generated from IRAS.

For studies involving Northern Ireland only – this option should be selected for studies involving CE marked devices that also involve procedures additional to the normal conditions of use of the device, that are also invasive or burdensome (Post Market Studies).

MHRA approval is not always required in the case of:

- Medical devices manufactured "in-house" in a healthcare establishment
- Clinician led off-label use of a medical device.

The need for MHRA approval will depend on the purpose of the investigation. Guidance on whether MHRA approval is required can be found on the MHRA website at:

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

Where research involves in-house devices or clinician-led off-label use, applicants are advised to contact MHRA Devices to discuss the purpose of the investigation and determine whether MHRA

approval is required. Contact details for MHRA Devices are on the website (see link above).

Pilot of coordinated assessment pathway for clinical investigations of medical devices: the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) are working together to test a coordinated assessment pathway that will streamline the review of clinical investigations of medical devices. To find out more and register your interest visit the MHRA website.

It is no longer possible to create a new application for a **Combined trial of an investigational medicinal product and an investigational medical device (IMP/Device trial)** using this part of IRAS. If you have an existing CTIMP or IMP/Device trial project and have not yet submitted your MHRA Devices Form you will no longer be able to do so here.

All IMP/Device trials now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

Combined review applications for IMP/Device trials.

If you are completing your initial application using the combined review service for an IMP/Device trial, **please select this option to complete the MHRA Devices form**. The MHRA Devices form should then be uploaded as part of the supporting documents that accompany your combined review submission.

For more detailed instructions on how to prepare an IMP/Device trial through the combined review service please refer to the guidance on IRAS Help.

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Application to Gene Therapy Advisory Committee

If your application is for ethical approval of a **gene therapy clinical trial** you must apply to the

Gene Therapy Advisory Committee (GTAC). GTAC is the UK national REC for gene therapy clinical research according to regulation 14(5) of The Medicines for Human Use (Clinical Trials) Regulations 2004. This means that GTAC is the main REC for gene therapy clinical trials.

If you select GTAC in Question 4, do not select the option to apply to another Research Ethics Committee.

The option to apply to GTAC is only available where Question 2 indicates that the study is a clinical trial of an investigational medicinal product.

Gene therapy medicinal products

Gene therapy medicinal products are defined in Part IV of Directive 2003/63/EC (amending Directive 2001/83/EC) as follows:

"...[a] gene therapy medicinal product means a product obtained through a set of manufacturing processes aimed at the transfer, to be performed either in vivo or ex vivo, of a prophylactic, diagnostic or therapeutic gene (i.e. a piece of nucleic acid), to human/animal cells and its subsequent expression in vivo. The gene transfer involves an expression system contained in a delivery system known as a vector, which can be of viral, as well as non-viral origin. The vector can also be included in a human or animal cell."

Applying to GTAC

For guidance on applying to GTAC please refer to: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/.

The application form for GTAC in IRAS is identical to that for any other CTIMP submitted to a recognised REC. There are however some differences in submission procedures:

- There is an extended time period of 90 days for ethical approval.
- Electronic submission of **all** documents is required.

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Application to the Confidentiality Advisory Group (CAG)
Introduction

Section 251 of the NHS Act 2006 re-enacted Section 60 of the Health & Social Care Act 2001. These powers allow the Secretary of State for Health to make regulations to set aside the common

law duty of confidentiality for medical purposes where it is not possible to use anonymised information and where seeking individual consent is not practicable. Approval of applications under Section 251 will only be considered where anonymised data will not suffice and consent is genuinely not practicable.

The Health Research Authority (HRA) established the Confidentiality Advisory Group (CAG) to review applications and provide advice to the HRA in respect of this function. The HRA will also be able to make research decisions to set aside the common law duty of confidentiality under the Regulations on behalf of the Secretary of State, following advice from CAG.

Applications receiving approval from the HRA under the resulting Regulations (Health Service (Control of Patient Information) Regulations 2002) are referred to as having obtained "Section 251 support".

For more information about CAG please refer to:https://www.myresearchproject.org.uk/help/hlpconfidentiality.aspx

When should you apply to the CAG?

You should apply to CAG if you need to access identifiable patient data relating to people living in, or receiving healthcare in, England and Wales without explicit consent, prior to the disclosure of confidential information.

***IMPORTANT: When you select the application for the Confidentiality Advisory Group (CAG) at filter question 4 this triggers a secondary question asking "Will you be seeking data from the Hospital Episodes Statistics (HES) or Secondary Uses Service (SUS)?" you should always select "no" to this secondary question. ***

For detailed guidance please refer to: https://www.myresearchproject.org.uk/help/hlpconfidentiality.aspx
Additional guidance and advice is available from the Confidentiality Advice Team. Contact details for this team are provided via the links above and on the IRAS Contact Us page.

Applications to CAG can be made simultaneously to applications made to the Research Ethics Committee (REC).

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Select this option if you wish to conduct research within HM Prison and Probation Service (HMPPS). You are required to formally apply for research approval to the HMPPS National Research Committee (NRC).

NRC process
The NRC process applies to research that has been commissioned and funded both internally and by external researchers/agencies. It applies to research across HMPPS (including headquarters) and all community-based/custodial providers in England and Wales, this includes research involving CRCs and their subcontractors, Contracted Prisons, Young Offenders' Institutions (YOIs) and, from October 2017, Secure Training Centres (STCs).

Application process
All applications should be sent to the National Research mailbox for processing. The NRC runs on a monthly cycle, applications should be submitted by the end of the month, they will then be processed and reviewed during the following month. Feedback on applications will normally be sent by the end of the month after they were submitted e.g. applications received between 1st and 31st January will be processed and reviewed in February, with feedback sent to the applicant by the 28th February.

The application form must be accompanied by the researchers' CVs, any ethical approvals, any questionnaires/interview schedules and consent forms/information sheets that have already been devised.

All student applications below doctoral level need to be supported by an MoJ/HMPPS business lead in order to be considered. This business support needs to come from a senior member of staff who is willing to state that they believe the research is going to be of benefit to HMPPS and will have minimal resource demands. Due to the potential volume of student applications, the NRC is not able to assist with student applications below doctoral level that do not have this business support.

Reviewing Applications: Approval Criteria
The following criteria are considered when reviewing applications:
Links to HMPPS priorities: research should be of significant benefit to HMPPS policy/business. Researchers must ensure that their research has a clear link to HMPPS business priorities or explain how their research could support potential future business priorities.
Resource demands: The demands on staff and resources must be manageable, and proportionate to the profile of the subject area and the potential benefits from the research.

Overlap with existing research: The project must avoid duplicating or conflicting with other current research studies.
Methodological robustness: The project must be of sufficient quality (in terms of methodological rigour).
Data Protection/Security: Data protection and security issues must have been considered and addressed.
Ethics: Ethical issues must have been reviewed and approved. Researchers must make clear the ethical guidelines under which they will be operating.
Researcher skills/competencies: Researchers must have the necessary skills and experience to undertake the proposed research

Applications can either be approved (with or without modifications), declined or a request for further information can be made. A large proportion of applications are required to provide further information due to a lack of detail in the application form. This extra information is usually in relation

to the methodology, in particular sampling, the benefits to HMPPS and data protection issues.

Applications are usually declined due to insufficient links to HMPPS business priorities, concerns about the rigour of the proposed methodology or due to a lack of detail on the application form. When research is not approved, reasons will usually be given. However, HMPPS reserves the right not to explain the reasons for refusing a research proposal when there are any sensitivity and/or security issues.

Consideration will be given to one resubmission per research topic. When resubmitting an application, the reasons for the previous rejection must be fully addressed.

Accessing the Frontline

Contact should not be made with potential participants until formal approval has been granted by the NRC or other the approving body. When contacting sites to facilitate access, copies of the approval should be provided.

The decision to grant access to prison establishments, NPS divisions or CRC areas (and the offenders and practitioners within these establishments/divisions/areas) ultimately lies with the Governing Governor/Director of the establishment or the Deputy Director/Chief Executive of the NPS division/CRC area concerned.

The decision to grant access to existing data lies with the Information Asset Owners (IAOs) for each data source. Data Sharing Agreements should be established where necessary.

The NRC cannot facilitate access on behalf of researchers.

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ARSAC Preliminary Research Assessment (PRA) Form

Where the research involves the administration of radioactive substances, sponsors are required to gain approval from the Administration of Radioactive Substances Advisory Committee. Further information on the requirements are available on the ARSAC website.

The ARSAC Preliminary Research Assessment (PRA) form is automatically generated in IRAS when the project filter has been completed to indicate that the study involves the administration of radioactive substances. The ARSAC Preliminary Research Assessment (PRA) form should be submitted through the ARSAC online portal at the same time as ethical review has been submitted to the REC.

For further guidance, please visit the ARSAC website or contact the ARSAC Support Unit. ARSAC contact details are available on the Contact Us page.

Clinical Trials of Investigational Medicinal Products (CTIMPs) and Combined trials of an investigational medicinal product and an investigational medical device (IMP/Device trials)

It is no longer possible for CTIMP or IMP/Device trial applications to be made using this part of IRAS. If you have an existing CTIMP or IMP/Device trial project and have not yet submitted your MHRA Medicines, IRAS, REC or GTAC forms (as applicable), you will no longer be able to do so here.

All CTIMPs and IMP/Device trials now need to apply using the combined review service, which can be accessed using the new part of IRAS. Please use the guidance on the HRA website for instructions on how to apply for combined review.

If you have any queries related to applying for combined review, please contact cwow@hra.nhs.uk.

Please note that there is no change in the process to prepare or submit an application to ARSAC, and this should still be done using the standard part of IRAS. If you are starting either a new CTIMP or IMP/Device trial application involving the use of ionising radiation, your application to the REC and MHRA should be made using the combined review service via the new part of IRAS. Further details can be found on IRAS help.

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IMPORTANT

In the secondary question asking "Will you be seeking data from the Hospital Episodes Statistics (HES) or Secondary Uses Service (SUS)" you should always select "no".

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IMPORTANT

In the secondary question asking "Will you be seeking data from the Hospital Episodes Statistics (HES) or Secondary Uses Service (SUS)" you should always select "no".

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IMPORTANT

In the secondary question 4a asking "Will you be seeking data from the Hospital Episodes Statistics (HES) or Secondary Uses Service (SUS)" you should always select "no". Please return to question 4a and revise your response.

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Research requiring approval/management permission for the NHS but not ethical review

The following types of research project do not require application for ethical review but still require approval/management permission for the NHS, if they are undertaken in or through an NHS organisation:

Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.

Samples/data must be non-identifiable to the researcher at point of access, otherwise further ethical review of the project is required.

Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.

Data must be non-identifiable to the researcher at point of access otherwise further ethical review of the project is required.

Research involving previously collected, non-identifiable information

Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

Research involving previously collected, non-identifiable tissue samples

Research limited to use of previously collected, non-identifiable material consisting of or including cells in accordance with the terms of donor consent is generally excluded from REC review.

However, REC review would be required if any of the following applied:

(a) Consent for research has not been given, or the research is not within the terms of the consent

(b) The samples will be held on premises in England, Wales or Northern Ireland without a licence from the Human Tissue Authority to store relevant material for scheduled purposes

(c) The research also involves removal, storage or use of new samples from the living or the deceased

(d) The research also involves use of identifiable information held with the samples.

Research involving acellular material

Research limited to acellular material (e.g. plasma, serum, DNA) extracted from tissue previously collected in the course of normal care is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research.

This exception applies to research undertaken by staff within a care team using samples previously collected for clinical purposes from their own patients or clients, provided that the samples/data are anonymised or pseudonymised in conducting the research.

However, REC review would be required if the research involved:

(a) Collection of tissue samples from patients in order to extract acellular material for the research

(b) Collection of information from patients

(c) Use of previously collected information from which patients could be identified by the researchers

(d) Analysis of DNA in material from the living, where consent for research is not in place from the person whose body manufactured the DNA

Research involving the premises or facilities of care organisations

REC review is not required for research involving use of or access to a care organisation's premises or facilities, provided that review is not required under any other applicable legal or policy requirement. For example, a Phase 1 clinical trial undertaken by a Contract Research Organisation on premises rented from a NHS Trust would legally require REC review under the Clinical Trials Regulations. But research undertaken by a university department on NHS premises, involving healthy volunteers not recruited as NHS patients and not subject to any legal requirements, would not require review by a REC within the UK Health Departments' Research Ethics Service and could be reviewed by the university's research ethics committee.

Research involving staff as participants

REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role.

Exceptionally, the Research Ethics Service may accept an application for review of research involving staff at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues. Agreement should be sought from the responsible operational manager for the REC centre prior to submission of the application. Requests should be sent by email, including a summary of the research proposal (maximum one page) and explanation of why the project raises significant issues which cannot be managed routinely in accordance with established guidelines and good practice, and requires ethical consideration and advice from a REC. Contact points for operational managers are

provided on the Health Research Authority (HRA) website

Researchers in Higher Education Institutions (HEIs) are advised to check whether, under their institution's policy and internal arrangements, ethical review is required by their HEI research ethics committee.

Please indicate in question {QNumber(Guid_Sieve_Q_4_B)} whether any of the above apply to your project. If not, please return to question {QNumber(Guid_Sieve_Q_4)} and select the option to apply for ethical review.

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Research requiring approval/management permission for the NHS but not ethical review

The following types of research project do not require application for ethical review but still require approval/management permission for the NHS, if they are undertaken in or through an NHS organisation:

Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.

Samples/data must be non-identifiable to the researcher at point of access, otherwise further ethical review of the project is required.

Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.

Data must be non-identifiable to the researcher at point of access otherwise further ethical review of the project is required.

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Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

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Research limited to use of previously collected, non-identifiable material consisting of or including cells in accordance with the terms of donor consent is generally excluded from REC review.

However, REC review would be required if any of the following applied:

(a) Consent for research has not been given, or the research is not within the terms of the consent

(b) The samples will be held on premises in England, Wales or Northern Ireland without a licence from the Human Tissue Authority to store relevant material for scheduled purposes

(c) The research also involves removal, storage or use of new samples from the living or the deceased

(d) The research also involves use of identifiable information held with the samples.

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Research limited to acellular material (e.g. plasma, serum, DNA) extracted from tissue previously collected in the course of normal care is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research.

This exception applies to research undertaken by staff within a care team using samples previously collected for clinical purposes from their own patients or clients, provided that the samples/data are anonymised or pseudonymised in conducting the research.

However, REC review would be required if the research involved:

(a) Collection of tissue samples from patients in order to extract acellular material for the research

(b) Collection of information from patients

(c) Use of previously collected information from which patients could be identified by the researchers

(d) Analysis of DNA in material from the living, where consent for research is not in place from the person whose body manufactured the DNA

Research involving the premises or facilities of care organisations

REC review is not required for research involving use of or access to a care organisation's premises or facilities, provided that review is not required under any other applicable legal or policy requirement. For example, a Phase 1 clinical trial undertaken by a Contract Research Organisation on premises rented from a NHS Trust would legally require REC review under the Clinical Trials Regulations. But research undertaken by a university department on NHS premises, involving healthy volunteers not recruited as NHS patients and not subject to any legal requirements, would not require review by a REC within the UK Health Departments' Research Ethics Service and could be reviewed by the university's research ethics committee.

Research involving staff as participants

REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role.

Exceptionally, the Research Ethics Service may accept an application for review of research involving staff at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues. Agreement should be sought from the responsible operational manager for the REC centre prior to submission of the application. Requests should be sent by email, including a summary of the research proposal (maximum one page) and explanation of why the project raises significant issues which cannot be managed routinely in accordance with established guidelines and good practice, and requires ethical consideration and advice from a REC. Contact points for operational managers are provided on the Health Research Authority (HRA) website

Researchers in Higher Education Institutions (HEIs) are advised to check whether, under their institution's policy and internal arrangements, ethical review is required by their HEI research ethics committee.

Please indicate in question {QNumber(Guid_Sieve_Q_4_B)} whether any of the above apply to your project. If not, please return to question {QNumber(Guid_Sieve_Q_4)} and select the option to apply for ethical review.

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NHS or non-NHS site?

A research site is defined as the single organisation *responsible* for conducting the research at a particular locality.

NHS research sites would typically be:

- A NHS Trust (in England or Wales)
- A NHS Health Board (in Scotland)
- A Health and Social Care Trust (in Northern Ireland)
- A GP practice

- A Strategic Health Authority in England (for public health, epidemiology or needs assessment studies)

- A prison establishment in England or Wales.

If your project will involve NHS/HSC Participant Identification Centres (PICs), you should answer 'yes' at this question.

The *research site* is not necessarily the *location* where research activities will actually take place. For example, in a research project by practice nurses from GP practices, interviews with participants may take place in the participant's home, but the research site would be the GP practice, because the GP practice would be responsible for the research activity.

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- The National Institute for Health and Care Research (NIHR) invests in world-leading facilities and expertise which make up the NIHR infrastructure and support research in the UK. Further details are available on the NIHR website.

- Some types of NIHR infrastructure funding also cover the research costs of studies taking place within that infrastructure.

- If all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research, for example NHS Support costs) for this study are provided by an NIHR Biomedical Research Centre, Applied Research Collaboration, NIHR Patient Safety Research Collaboration or an NIHR HealthTech Research Centre in all study sites; an application for NIHR Research Delivery Network (RDN) support should not be required. In this case, select 'yes' to this question. By doing so your study will not be considered for additional NIHR support through the RDN.

- If all of the research costs and infrastructure costs (funding for the support and facilities needed to carry out research, for example NHS Support costs) for this study are not funded by an NIHR Biomedical Research Centre, Applied Research Collaboration, NIHR Patient Safety Research Collaboration (PSRC) or an NIHR HealthTech Research Centre in all study sites; your study may be eligible for consideration for NIHR Research Delivery Network (RDN) support and inclusion in the NIHR RDN Portfolio. Refer to the Eligibility Criteria for NIHR Research Delivery Network Support.

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The NIHR Research Delivery Network (RDN) enables the health and care system to attract, optimise and deliver research across England, for example by supporting the successful delivery of high-quality research as an active partner in the research system.

If you plan to run your study through the NIHR RDN, you should contact your regional network as early as possible for advice and support.

If you select “yes” to this question, information from your IRAS submission will be automatically shared with the NIHR RDN and used to determine whether your study is eligible for NIHR RDN support and inclusion on the NIHR RDN Portfolio. The NIHR RDN will notify you of their decision by email.

For support and advice contact supportmystudy@nihr.ac.uk or the relevant national coordinating functions in the UK Administrations.

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The NIHR Research Delivery Network (RDN) enables the health and care system to attract, optimise and deliver research across England e.g. by supporting the successful delivery of high-quality research, as an active partner in the research system.

You have indicated that your study has sites located in England. To apply for support for the English sites, select "Yes" to this question and your IRAS Form, letter from the funder and research protocol will be passed to the NIHR RDN. They will contact you about your application via email.

For support and advice contact the relevant national coordinating functions in the UK Administrations or supportmystudy@nihr.ac.uk.

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Children

Please answer Yes if the research will include participants aged under 16, or use of their samples or data.

You should still answer Yes if some or all of the participants will be able to consent for themselves under the Gillick principles. Further guidance about this is available in Part B Section 7 of IRAS, which covers issues in the inclusion of children in research.

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Adults unable to consent for themselves -

Please answer Yes if it is possible that the research could ***at any stage*** include adults (aged 16 or over) who are unable to consent for themselves due to physical or mental incapacity (including temporary incapacity).

You should still answer Yes if participants will be able to give consent initially but you plan to undertake further research procedures on or in relation to such participants (including collection of new samples or data) following loss of capacity to consent during the study. If participants would be withdrawn from the study following loss of capacity, you may answer No. For guidance on retaining samples or data already collected at the point capacity is lost, please refer to the guidance on Question A35 in IRAS.

Where research involves adults unable to consent for themselves, the application and approval requirements differ according to:

- Whether your research is a clinical trial of an investigational medicinal product (CTIMP) or a non-CTIMP, and
- In which countries of the UK the research sites will be located.

Please indicate, in answer to the supplementary question, which countries you expect the research sites to be located in.

Guidance

Detailed guidance on ethical review of applications involving adults unable to consent for themselves is available on the Health Research Authority (HRA) website at:

- https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/
- https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/

A summary of key points is below.

Booking the ethics application

Please refer the Health Research Authority (HRA) website for guidance on booking your application: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/

When booking, please indicate at the relevant questions that the research may include adults unable to consent for themselves and which UK countries are involved.

The application will be allocated to review by a "flagged REC" (see below). Applicants for research in England and Wales may indicate a preference for a particular flagged REC when booking the application.

Flagged RECs

The HRA has appointed a panel of flagged RECs to review all new research potentially including adults unable to consent for themselves. You can refer to the REC Directory to search for a REC flagged to review a particular type of research: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/

Where the research is a CTIMP, the application will be allocated to a committee which is *both* recognised by UKECA for review of CTIMPs *and* flagged for review of research involving adults unable to consent for themselves.

Where the research is a CTIMP to be conducted at one or more sites in Scotland and the Chief Investigator is professionally based in Scotland, it must be reviewed by the Scotland A REC.

Approval requirements (CTIMPs)

The inclusion of adults unable to consent for themselves in any part of the UK is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004. *The Mental Capacity Act 2005 (England and Wales), the Mental Capacity Act (Northern Ireland) 2016, and the Adults with Incapacity (Scotland) Act 2000 have no application to CTIMPs*.

The ethical review must consider whether the trial is justified having regard to the conditions and principles specified in Part 5 of Schedule 1 to the Regulations. These include provisions for informed consent to be given by the subject's legal representative. A definition of "legal representative" for this purpose is given in Part 1 of Schedule 1.

Applicants should give information about the inclusion of adults unable to consent in Part B Section 6 of the application form.

Approval requirements (all other NHS and non-NHS research)

Approval requirements for non-CTIMPs differ across the UK as follows:

England and Wales:

- In England and Wales, approval is required by an "appropriate body" under section 30 of the Mental Capacity Act 2005 (MCA) for any research, whether NHS or non-NHS research.
- This approval must be given by a NHS REC in England or Wales, even where the research does not involve NHS patients.
- For guidance on the research provisions of the MCA, see chapter 11 of the Code of Practice, available at https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice

Scotland:

- In Scotland, approval is required under section 51 of the Adults with Incapacity (Scotland) Act 2000. *This approval must be given by the Scotland A REC*.

Northern Ireland:

- In Northern Ireland, approval is required under section 132 of the Mental Capacity Act (Northern Ireland) 2016, and the Code of Practice - MCA (NI) 2016 - Money & Valuables and Research
- Where the research will be taking place in Northern Ireland only, it should be reviewed by a Health and Social Care (HSC) REC in Northern Ireland.
- Where non-CTIMP research will be taking place in Northern Ireland and another UK country, follow the process in the table below.

The table below summarises the process for non-CTIMPs taking place in different UK countries.

Countries where sites located	**Application process**
England and/or Wales only	Apply to any flagged REC in England or Wales.
Scotland only	Apply to a designated REC in Scotland.
Northern Ireland only	Apply to any HSC REC in Northern Ireland.
England and Wales	Apply to any flagged REC in England or Wales.
England/Wales/Northern Ireland and Scotland	Two applications should be made: 1. The England/Wales/Northern Ireland application should be made to a flagged REC in England or Wales or Northern Ireland 2. The Scotland application should be made to a designated REC in Scotland. Separate versions of the REC application form in IRAS should be submitted with separate REC reference numbers. Both applications may be submitted at the same time or they may be submitted consecutively; with the first opinion being given in advance of the second application being submitted. The applications will be reviewed separately having

	regard to the relevant legislation. Any favourable opinion with respect to including ALC will apply only to England/Wales/Northern Ireland or Scotland respectively. Different opinions may be given in regard to the inclusion of adults who lack capacity/adults with incapacity. A favourable ethical opinion from either REC means that the study has a favourable ethical opinion to proceed in England/Wales/Northern Ireland **and** Scotland but if the other REC gives an unfavourable opinion, it is not permitted to include adults who lack capacity/adults with incapacity in the country which did not give a favourable ethical opinion. When an application which involves; adults who lack capacity/adults with incapacity, is being undertaken in England/Wales/Northern Ireland and Scotland, the requirement for dual review should be discussed with the applicant. The second REC to undertake the review should request the favourable opinion from the first REC by contacting the Approvals Officer/REC Manager. The favourable opinion letter should be made available to the REC members of the second REC when reviewing the application. Discussion should be undertaken between the REC Chairs of the two RECs if there is any disparity. Any substantial amendments which do not relate to MCA/AWI need only be submitted to one REC and should not be submitted to both.
England/Wales and Northern Ireland	Apply to any flagged REC in England/ Wales or Northern Ireland Only one application is required.

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Prisoners

For this purpose, a prisoner or young offender is defined as any inmate of the prison systems of England and Wales, Scotland or Northern Ireland. It does not include patients detained under the Mental Health Act at special hospitals or other psychiatric secure units, or juvenile offenders detained in local authority secure accommodation or secure training centres.

The Offender Health Research Network (OHRN) publishes guidance on the various approvals and permissions required to conduct research involving prisoners in England and Wales, and may be able to assist with specific queries. Further information is at http://www.ohrn.nhs.uk

Except in Scotland, ethics applications involving prisoners should be booked with the Central Booking Service (CBS), which will arrange allocation to one of the RECs designated by NRES to review such research. In Scotland the application may be made direct to the relevant REC if it is within a single domain; if it is multi-domain, it should be allocated through CBS.

Health research involving prisoners or young offenders should relate directly to their health care and be of such a nature that it could only be conducted in this population.

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Educational projects

IMPORTANT: Eligibility Criteria for Student Research

Undergraduate Level: Health and social care research applications from students working at undergraduate level are no longer being accepted for Research Ethics Committee (REC) review; Health Research Authority and Health and Care Research Wales (HRA and HCRW) Approval; and/or R&D study-wide review in Scotland and Northern Ireland.

Master's Level: Applicants should complete the Student Research Toolkit in the first instance, to check eligibility. Some health and social care research applications from students working at Master's level are no longer being accepted for Research Ethics Committee (REC) review; Health Research Authority and Health and Care Research Wales (HRA and HCRW) Approval; and/or R&D study-wide review in Scotland and Northern Ireland.

Doctorate Level: Health and social care research applications from students working at doctorate level are being accepted for Research Ethics Committee (REC) review; HRA and HCRW Approval; and/or Research and Development (R&D) study-wide review in Scotland and Northern Ireland. Applicants may find it helpful to complete the Student Research Toolkit.

Please visit the Health Research Authority (HRA) website – Student Research for further guidance. For student research below doctorate level, it is very important to complete the Student Research Toolkit before proceeding with your application form.

Educational Projects

An educational project is a project where the primary purpose is for obtaining an educational qualification. This includes doctoral research. Studies where the main purpose is to undertake specific research, and the educational qualification is secondary, do not fall into this category.

If the project is an educational project answer 'Yes' to question 9.

When you answer 'Yes', a free text box will appear as well as an additional question – question 9a.

- In the free text box, please provide information about the involvement of the student(s) and please clarify whether the project is part of an individual student qualification or whether the project is group research (this means a project in which a number of students, possibly over different year groups, are playing a part in different aspects of the research).

- At question 9a 'Is the project being undertaken in part fulfilment of a PhD or other doctorate?', answer 'Yes' if the project is being undertaken as part of a PhD or other doctorate. Answer 'No' if the project is being undertaken at a master's level. Where the project is being undertaken as part of a master's and you answer 'No' at question 9a, you need to ensure that you have completed the Student Toolkit before you proceed with your application. The Student Toolkit also includes supplementary declarations that need to be completed and submitted alongside this application.

Social Care Research

Student research within the field of social care should ordinarily be reviewed by a University REC, rather than the Social Care REC. However, student research within the field of social care in Northern Ireland should be reviewed by a HSC REC, unless exempt from HSC REC review according to 'Governance Arrangements for Research Ethics Committees (GAfREC)' (i.e. study only involves staff); staff only studies in social care would be reviewed by a University REC.

Chief Investigator

According to section 9.3 of the UK Policy Framework for Health and Social Care Research, students should not normally take the role of Chief Investigator at any level of study, as this function should be undertaken by supervisors or course leaders. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or doctoral-level study while employed by a health and social care provider or university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship. More information is available on the Health Research Authority (HRA) website – Student Research

Normally the student's academic supervisor should be named as the Chief Investigator and should

complete both the CI and supervisor declarations in Part D.

Guidance last updated: 01 September 2021

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Research funded by the US Department of Health and Human Services

There are special arrangements for review of research with funding support from the US Department of Health and Human Services (DHHS).

Applying to a REC with OHRP registration

- All such applications should be booked for review with the UK Health Departments' Research Ethics Service Online Booking Service and allocated to a Research Ethics Committee (REC) which is flagged for this purpose. All flagged RECs are registered with the US Office for Human Research Protections (OHRP) as an Institutional Review Board (IRB) / Independent Ethics Committee (IEC).

- A listing of the NHS RECs in the UK flagged as IRBs is available via the REC Directory on the Health Research Authority (HRA) website.

- Some applications will require review by a REC that is registered with the OHRP as well as being flagged for a particular study type (e.g. CTIMPs in healthy volunteers)

Requirements for Federal Wide Assurance at research sites

- Each host organisation participating in the study must have Federal Wide Assurance (FWA) in place with the OHRP. An FWA is a general commitment by the institution to comply, in the management and conduct of human participant research, with the DHHS Protection of Human Subjects regulations.

- Guidance on how to register for FWA at a non-US research site is available on the U.S. Department of Health & Human Services website.

- Sponsors and Chief Investigators are strongly encouraged to make early contact with R&D offices at each planned research site to discuss preparations for the study. In order to obtain

an FWA, the research institution must give details of the IRB/IEC(s) undertaking ethical review of DHHS-funded research to be conducted at the site. Therefore, the FWA at each site must list the REC responsible for reviewing the current study and this REC must be registered with the OHRP.

- It is open to R&D offices to list all the RECs flagged as IRB Registered on their FWA. This can be done in advance of submitting the REC application and allocation to a particular REC for review and may reduce start-up time.

- Organisations with an existing FWA may update their FWA at any time to include additional IRB/IECs. To update FWA, a revised version of the form should be submitted to OHRP.

Further advice

- For further advice about the requirements of the DHHS or the process of registration for FWA, contact the OHRP directly.

- Details of registered IRBs and approved FWAs are available in the DHHS's OHRP Database.

Guidance last updated: 25 August 2020

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Processing identifiable data without consent

If your project involves access to identifiable patient data relating to people living or receiving care and treatment in England and Wales without explicit consent, you may need to apply to Health Research Authority (HRA) for approval to process data without consent and an application should be made to the Confidentiality Advisory Group (CAG).

For details of Section 251 of the NHS Act 2006 and supporting Health Service (Control of Patient Information) Regulations 2002, how it regulates the control of identifiable patient data and how it may impact on your research, please refer to the HRA website. Further guidance is available from

the information button next to the option on applying to CAG in Question 4 of the Project Filter.

An application for approval from HRA to process data without consent does not negate the need for a favourable opinion from a REC or approval/permission from the host organisation.

The HRA provides a free e-learning module explaining the legislation and information governance considerations relating to use of personally identifiable data in health research which can be accessed from the HRA website.

Page last updated: 05 June 2019

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