University of Kentucky Human Research Protection Program (HRPP)

IRB Member

Topic Categories

Applicable Human Research Protection Program (HRPP) Regulations, Laws, Codes, and Protections

Scientific/ Disciplinary Expertise and Representative Capacity

Conflict of Interest (COI)

Institutional Support

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IRB Reporting Requirements

Vulnerable Populations

Informed Consent

FDA Regulated Research

Community Based Participatory Research

Communication and outreach to current and prospective research participants

Applicable HRPP Regulations, Laws, Codes, and Protections

1. What rules or guidelines are you expected to follow?

Federal Regulations that Apply to All UK Human Subject Research

Department of Health and Human Services (DHHS) 45 CFR 46:

Subpart A – "Common Rule" IRB Operations, Approval Criteria, Informed Consent

Subpart B - Fetuses/Pregnant Women/Neonates

Subpart C - Prisoners

Subpart D - Children

Regulations that are applicable to select protocols:

A. Food and Drug Administration regulations

B. Health Insurance Portability Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA) or General Data Protection Regulation (GDPR)

Funding Agency Requirements:

- Department of Defense (DoD)
- US Department of Education (DoED)
- Environmental Protection Agency (EPA)
- US Department of Justice (DOJ); National Institute of Justice (NIJ); Bureau of Prisons (BOP)
- Department of Energy (DOE)

State Law or Local Policy

State laws regarding legally authorized representatives

Department of Corrections (DOC) consent requirements

School District Research Review requirements

University of Kentucky Policies and Procedures and Regulations

A. President Level Administrative Regulations (AR):

- AR 7:1 Research Misconduct
- AR 7.2 Research Conflict of Interest and Financial Disclosure Policy
- AR 7:4 Human Research Subject Protection and Institutional Review Boards
- AR 7.9 Institutional Conflict of Interest

B. Vice President for Research (VPR): University of Kentucky Human Research Protection Program Comprehensive Plan

C. IRB/ORI:

- Standard Operating Procedures
- Application Forms
- IRB SURVIVAL HANDBOOK – Guidance Documents by Topic

2. How did UK transition to the Revised Common Rule?

We allowed pre-2019 research to continue through conclusion under the old rule. If an investigator chose to transition a pre-2019 study to the revised rule, the could close the study and re-submit as a new protocol.

3. What ethical standards or guides does the IRB follow?

The above research regulations are based on the ethical principles set forth in the Nuremberg Code, Declaration of Helsinki, and the Belmont Report issued by the National Commission for the Protection of Human Subjects 1979. Belmont outlines three ethical principles that are central to human subject protection.

- **Respect for persons** involves recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy.
- **Beneficence** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
- **Justice** requires that the benefits and burdens of research be distributed fairly.

Remember/Consider….

Proposed research that is compliant with the regulations may still have ethical concerns.

Researchers should apply ethical principles and standards appropriate

4. What is an example of how the IRB applies the Belmont Principles?

- We question if consent process is designed to respect subject autonomy and ensure those with diminished autonomy have appropriate protections and safeguards.
- We spend a lot of time on risk – benefit analysis, considering risk and benefit to subjects and society; the magnitude and probability of possible harm, and potential efforts to minimize risks. We look to see if the study is designed properly to minimize risk and maximize gain.
- In considering justice we examine the study population and recruitment plan to determine if risks/benefits are distributed fairly and no particular group is being unjustifiably exclude or being targeted for convenience or due to their compromised position.

5. What is the process for when determining whether an activity is under the purview of the IRB?

1. See What Needs IRB Review website for resources & contact ORI with questions on application of regulations & UK Policy
2. If unclear, submit a Not Human Research (NHR) determination form on REDCap
3. The ORI Director or IRB Chair provides an official determination on whether an activity meets applicable regulatory definitions of human subject research.
4. The ORI communicates the decision to the investigator via phone, email, or hard copy memo.

The PI may use "What Needs Review" resources to make a preliminary decision; he/she may contact ORI staff, IRB Chair/Vice Chair or member for advice on application of the federal regulations and UK

policy. The ORI What Needs IRB Review Website includes, Guidance, Videos, Tables, Forms, and other resources.

PI may submit a Not Human Research (NHR) determination form or send an e-mail requesting a determination to IRBSubmission@uky.edu to obtain an IRB determination regarding need for review.

6. **What is meant by "Equivalent Protections"?**

Equivalent protections are regulatory or ethical systems that exist in countries outside of the United States to protect human research subjects that are ethically equivalent to those in the US. Equivalent protections may include regulation, law, ethical codes, and cultural standards.

Identify Applicable Requirements/Protections: If research is to be conducted at an international location, the investigator identifies local regulations, laws, or standards for human subject protection. The Office for Human Research Protections (OHRP) International Website includes tools for international research including **laws, regulations, and guidelines** from more than 100 countries; and **European General Data Protection Regulation (GDPR) Guidance**.

Cultural Consultation: The IRB obtains a cultural consultant to provide comments, concerns, translations, in writing to the IRB on protocols involving non-English speaking subjects, and/or subjects from a foreign culture.

7. **How does UK ensure the rights and welfare of participants are protected when the investigator is operating at a non-UK facility, is conducting collaborative research, or when oversight is shared with or deferred to another organization or IRB?**

In the IRB application, investigators include **letters of support** approving the conduct of research at non-UK facilities.

If research involves collaboration with any sites and/or personnel outside UK, then it is considered multisite research and IRB reliance issues will need to be addressed.

UK has procedures to define the responsibilities of collaborating institutions and to coordinate communication among responsible IRBs. UK IRB requires a written agreement to be completed between organizations involved in a reliance relationship. A **Reliance (or Authorization) Agreement** identifies and describes the respective authorities, roles, responsibilities, and methods of communication between an institution/organization providing the IRB review of research and a participating site relying on the institution/organization.

Federal policies require review by a single IRB for select multi-site research. Studies using an external IRB MUST register with the UK IRB.

The **ORI Single IRB Reliance** website provides tools, checklists, forms, sample agreements and guidance for navigating single IRB review.

Prior to allowing investigators to cede research to an external IRB, the IRB (with ORI assistance):

a. verifies information about ensuring initial and ongoing qualifications and Human Subjects Protection Training; and
b. verifies the external IRB is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). UK may agree to defer responsibility for IRB review to a non-

AAHRPP accredited institution's IRB for research that is not greater than minimal risk. To defer responsibility, the non-UK IRB must have an OHRP-registered IRB.

8. **When would an institution be considered "engaged" in research?**

   When its employees or agents for the purposes of the research project obtain:

   (1) data about the subjects of the research through intervention or interaction with them;

   (2) identifiable private information about the subjects of the research; or

   (3) the informed consent of human subjects for the research.

Scientific/ Disciplinary Expertise and Representative Capacity

1. **Who serves as the non-scientist member and who serves as the non-affiliated member of the IRB?**

   We have community members that are both non-scientist and unaffiliated with UK.

   The non-scientist must be present to have quorum.

   TIP: Regular members should know the name of the community member on his/her IRB.

2. **Who is involved in conducting scientific review at your institution?**

   The Department Chairperson/Faculty Advisor and the IRB.

   - Department Chairperson/Faculty Advisor attest that the science is meritorious and deserving of conduct in humans by considering the:
     - ✓ validity and utility of science;
     - ✓ availability and qualifications of personnel;
     - ✓ potential subject population; facilities and equipment;
     - ✓ ongoing mentoring and guidance; and
     - ✓ resolves issues prior to the IRB's receipt of the submission.
   - The IRB considers the scientific study design within context of human subject protection. IRB members draw on their own knowledge and disciplinary expertise to determine if research procedures are consistent with sound research design and the protocol has potential to yield the expected knowledge. When needed, the IRB seeks consultation from content experts.

3. **Does the IRB ever require consultations when reviewing research and when would a consultant be required?**

   Yes, when the IRB does not have the appropriate expertise for a certain type of research, or for a specific population, consultants with competence in special areas assist in the review. Need could be related to the protocol (biosafety, radiation safety, etc.), the population (cultural, vulnerable subjects), or protections (information safety). The consultants do not vote with the IRB and do not count toward a quorum at a convened meeting.

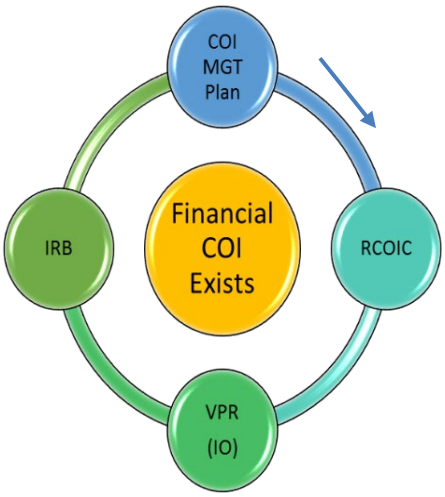
Conflict of Interest

1. **What is UK's policy on Research Conflict of Interest (COI)?**

UK actually has two policies on conflict of interest; one for **research investigators** and one for the **institution** itself.
Financial COI related to research of individual investigators is covered in **Administrative Regulation (AR) 7.2 - Financial Conflicts of Interest in Research**. The AR outlines procedures for defining, identifying, disclosing, managing, reporting and training regarding COI.
A potential or actual Conflict of Interest (COI) exists when a significant financial interest (as defined below) of an Investigator or a family member of the Investigator could directly and significantly affect the design, conduct, or reporting of research.
COI is under the authority of the Institutional Official, Vice President for Research, Dr. Ilhem Messaoudi Powers. Administered by the Office of Sponsored Projects Administration (OSPA). ORI & OSPA coordinate handling of Investigator COI for both funded and unfunded human subject research. Details are outlined in the COI coordination SOP. 💻**See the OSPA COI website for guidance.**

2. **How is researcher COI managed?**

The IRB application asks if any investigators or key study personnel have a Significant Financial Interest requiring disclosure and if the interests related to the proposed research?



1. If a financial COI exists and cannot be eliminated, the investigator and his/her dean or director propose a management plan.
2. All management plans are referred to the **Research Conflict of Interest Committee (RCOIC)** for review. ORI Reliance Manager, Jessica Williams represents human research on the RCOIC.
3. The RCOIC recommends a plan to the Institutional Official who makes the final decision on approval of the plan.
4. IRB does not complete its review and approval of the IRB application until it receives the final VPR approved management plan. The IRB may not change the approved plan, but, it may impose further restrictions/conditions on the protocol or disapprove the protocol.

3. **Does the institution (University of Kentucky) have a Conflict of Interest Policy?**

Yes, the Institutional COI policy is covered under **Administrative Regulation (AR) 7.9 Institutional Conflict of Interest (COI) Involving Research**

- It is under the authority of the Institutional Official, Vice President for Research, Dr.Ilhem Messaoudi Powers. Administered by the Office of Sponsored Projects Administration (OSPA).
- The institution requires select administrators to disclose significant financial interest (SFI).
- Review is conducted by the Institutional Conflict of Interest Committee (ICOIC)
- IRB Chair Terry Malone serves as liaison between IRB and ICOIC.

4. **Who has the ultimate authority regarding management of investigator conflict of interest?**

   For human subject research, the **IRB has the final authority** to decide whether the conflict of interest and approved management plan, if any, allows the research to be approved. The IRB may impose further restrictions on the protocol or disapprove the protocol. The IRB does not have the authority to disapprove the final VPR approved management plan but may require these additional protections.

5. **How is IRB member conflict of interest identified and handled at a meeting?**

   During new IRB member orientation, members are informed about the IRB member Conflicts of Interest policy. At orientation you are asked to sign a Conflict of Interest agreement indicating that you recognize that the protection of human subjects requires objectivity and you agree to disclose conflicting interests on a protocol by protocol basis. Signed COI Statements are maintained by ORI.

   COI at Convened Meetings:

   During convened meetings the IRB Chair prompts members to consider any conflict prior to reviews.

   A member with a conflict may be asked questions about the content of the protocol, and issues concerning the study, but must not be present beyond the questions and answers, and, other than to provide information, must not seek, inside or outside the meeting, to influence or affect the voting of non-conflicted members. The minutes must document the fact that the member left the meeting room during the final discussion and vote.

   These procedures apply to all types of reviews conducted at a convened meeting (e.g., Initial, Continuation, Modification, Unanticipated Problem, etc...).

   COI for Expedited & Exempt:

   The reviewer's signature line on the Exemption & Expedited Review Signature Page is prefaced by the following statement:

   "I am not aware of any conflict of interest that would prohibit me from reviewing and/or making a determination about the attached materials."

   The reviewer notifies ORI staff when she/he has a conflict of interest, and ORI staff contact a secondary reviewer to conduct the review.

6. **Is there a process for consultants to disclose conflicts?**

   Yes, ORI sends a COI disclosure and confidentiality agreement with the consultation request. If the consultant has conflicts impacting his/her ability to objectively review the protocol or provide input, he/she discloses the conflict and does not participate in the review.

Institutional Support

1. **Who is ultimately responsible for the HRPP?**

   Vice President for Research, Dr. Ilhem Messaoudi Powers, is the designated institutional official responsible for oversight and management of all aspects of UK research. The VPR establishes the mechanisms and framework for the HRPP and ensures enough resources to support it.

2. **How is authority communicated to the research community?**

The Human Research Protection Program (HRPP) Comprehensive Plan establishes the authority and independence as well as the level and scope of responsibility for the IRBs and describes the organizational structure for human research protection. Located on the VPR webpage: https://www.research.uky.edu/uploads/2018-university-kentucky-human-research-protection-program

3. **Who has the authority to approve research? Can decisions be overturned?**

The IRB has been granted authority to approve human subject research. If IRB has DISAPPROVED a protocol, no institutional entity may overturn the IRB's determination. The institution may disapprove research that has been approved by the IRB.

Resources and Education

1. How does the IRB learn of new or revised policies/procedures/regulations?

The ORI AAHRPP website has an Updated Policies page. ORI notify members via email communications, newsletters, and in-service education sessions. In some cases, the education staff member or ORI staff will present information at the IRB meeting.

ORI tracks and summarizes select draft and final regulations or guidance documents in a chronological table, Recent Changes at the Federal Level Impacting IRBs, available on the ORI Survival Handbook.

2. **What type of onboarding and ongoing training is provided?**

New members – Orientation session, online course & mentor

Vice Chair Orientation - Orientation session and resource binder

Monthly Medical Chair Meetings - provide ongoing education, updates, and discuss ethical or protocol-specific review issues to promote consistency.

Meeting Mini Sessions – brief educational updates on specific topics at the beginning of board meetings

IRB In-Service – education session provided twice a year to all members including alternates.

E-IRB Tutorials, Zoom sessions, & E-IRB Online Edge newsletter

IRB *Review* newsletter – monthly newsletter for all HRPP

IRB Member Minute – topical emails with cases, articles, special interest items

IRB Q & A of the Week – review questions

Quality Improvement, Periodic Review of HRPP & IRB Performance Evaluation

1. **What kinds of research compliance or quality improvement reporting is conducted?**

- **Directed Review:**
  The ORI Quality Improvement Program (QIP) conducts direct reviews at the request of the IRB, the Vice President for Research (VPR), or the ORI Director due to unusual circumstances, significant risks to subjects, routine failure on the part of an investigator to comply with federal and/or institutional requirements, or allegations or concerns about the conduct of the study.
- **Abbreviated Review (Wellness Check):**
  The ORI Quality Improvement Program (QIP) conducts wellness checks on randomly selected

protocols, with the goal of completing the assessment six months after the approval. Wellness checks are meant as an education opportunity to ensure compliance with regulations and prevent protocol violations as well as to aid in study organization.

- **Investigator Self-Assessment:**
  The Investigator self-assessment is a tool for researchers to identify gaps, areas for improvement or education needs.
- **Administrative Review:**
  These reviews are conducted to measure the effectiveness and/or efficiency of ORI/IRB procedures for protection of human subjects in research. The QIP Coordinator may periodically conduct a thorough examination of the IRB records, the E-IRB, and/or other materials to evaluate performance and compliance with federal regulations, institutional policy, etc.

2. **Is your performance as an IRB member periodically evaluated?**

   Yes, ORI sends all IRB members and staff a Performance Evaluation Questionnaire about once a year. We assess our own performance as well as that of members, chairs, and vice chairs on several attributes such as knowledge, adherence to regulations, attendance, participation, etc.

3. **Are the IRB members given feedback about the evaluation?**

   Yes, we (IRB members and ORI staff) are sent a report of the **aggregate results** by email.

4. **What is the process to submit suggestions, concerns, and questions regarding administrative, operational issues?**

   - IRB Determinations –IRB Chair or Reviewer

     Investigators may submit a written appeal to the convened IRB, including justification for changing the IRB decision. The appeal determination final.
   - Administrative/Operational/Procedural Issues or Subject Complaints- ORI Director Helene Lake-Bullock (859) 257-2978 or helene.lake-bullock@uky.edu
   - The ORI website includes a page specific for submitting concerns, suggestions, or questions which includes contact information as well as an anonymous online customer service submit form.

IRB Appointment, Operations, and General Review Concepts

1. **How easy is it to bring up questions and concerns at the meeting regarding a review being conducted?**

   Questions and concerns are encouraged.

2. **What does the IRB consider when evaluating whether recruitment materials/advertisements are appropriate?**

   The IRB assures that the advertisements do NOT:

   - state or imply a favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
   - include claims that the intervention is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device that are inconsistent with Food and Drug Administration (FDA) labeling.

- use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational;
- emphasize rewards or payments;
- include exculpatory language;
- include language implying IRB endorsement (e.g., study is IRB approved);
- promise a certainty of cure beyond what is outlined in the consent and the protocol; or
- promise or imply free medical care rather than specify procedures/care is provided at no cost.

Recruitment materials may state that subjects will be paid to compensate for their time and/or travel. For Phase I-III clinical trials and other significant risk research it is not permissible to state the amount to be paid to potential subjects. For all other research protocols, the IRB will make the decision of whether amount to be paid may be posted in the recruitment materials on an individual protocol basis.

3. How does the IRB determine if approval criteria are met?

a. The IRB application forms mirror the regulations so that we get the answers or justifications we need to make determinations.

b. The Criteria for Approval Checklist includes informed consent elements and the federally required criteria for approval:
   - Risks to subjects are reasonable in relation to anticipated benefits,
   - Subject selection is equitable
   - Adequate provisions are in place for seeking informed consent (including required and applicable additional elements)
   - The provisions for documenting informed consent/assent are appropriate.
   - Adequate provisions for protecting the privacy and confidentiality of subjects.
   - Safeguards included to protect rights and welfare of vulnerable subjects
   - Data & safety monitoring - Greater than minimal risk research or NIH funded/FDA regulated clinical investigations, adequate provisions are in place for monitoring the data collected

c. In addition, the IRB considers other applicable regulatory or protocol-specific requirements (FDA regulated device study, Department of Defense requirements, privacy regulations, etc.) qualifications of research personnel, adequacy of research setting, and signature assurance of chairperson or faculty advisor documenting scientific review.

4. Name a specific study design that can be ethically challenging for the IRB?

- **Cluster randomization** (large group randomization does not allow prospective consent from individuals studied)
- **Comparative Effectiveness** (SOC but is there risks from randomization itself; if so how can study design mitigate risk and is risk communicated in informed consent?)
- **Placebo Controlled in pediatric studies** (can't classify as category 2 as FDA does not consider there to be potential benefit)
- **Digital Device Studies** (is device a medical digital device that is being tested? Is a device or application being used to collect data? Are the terms of agreement for use of available apps consistent with informed consent confidentiality protections?)

5. What is the difference between protecting the privacy interests of participants and maintaining the confidentiality of data?

<u>Privacy</u> concerns people.

The following are considerations and strategies for respecting the privacy of potential participants.

- Consider the methods used or setting where potential participants are identified. What is the targeted study population's expectation of privacy, both in person and online?
- Only approach individuals known to you or make contact on behalf of someone the individual knows.
- Comply with privacy guidelines of applicable professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
- Access the minimum amount of information necessary.

<u>Confidentiality</u> concerns data.

Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. In the IRB research description, investigators describe their plan to preserve the confidentiality of identifiable data, including:

- controls on storage, handling, and sharing of data
- physical security measures (*e.g., locked facility, limited access*);
- data security (*e.g., password-protection, data encryption)* see *IRB Data Security Guidance*
- safeguards to protect identifiable research information (*e.g., coding, certificate of confidentiality*);
- procedures employed when sharing material or data, (*e.g., honest broker (if applicable), written agreement with recipient not to re-identify*); and
- measures that you will take to secure and safeguard confidentiality if protocol involves storing material or tissue/specimens/data for use in current or future research (how material will be destroyed or rationale for perpetual maintenance).

Initial Review, Continuing Review, Modifications

INITIAL CONVENED REVIEW

1. What is a controverted issue? Describe a controverted issue that came up at a meeting, the different points of view, and how the issue(s) was/were resolved.

A **controverted issue** is an issue that results in disagreement or opposing viewpoints among IRB members that are discussed during the IRB's deliberations. Regulations require a summary of controverted issues and their resolution to be included in IRB meeting minutes. The IRB discussions should revolve around the ethical and regulatory criteria for IRB approval, including but not limited to the provisions for minimizing risk, informed consent procedures, and protections against coercion or undue influence.

2. **Does the IRB review sensitive or controversial research (issues) you have reviewed lately?**

   Yes, in such cases the IRB may require a certificate of confidentiality or safeguards such as providing referral for counseling should a participant become upset.

3. **What criteria are used by the IRB to determine when a modification needs full review?**

   Any modification that is NOT deemed minor by the primary reviewer is subject to review by the IRB at a convened meeting. Minor modifications are considered eligible for expedited review. A minor change is one which makes **NO** substantial alteration in:

   - The level of risk to subjects;
   - The research design or methodology;
   - The informed consent process/documentation;
   - Safety and monitoring of subjects;
   - Privacy or data confidentiality;
   - The subject selection/population;
   - Qualifications of the research team;
   - The facilities available to support the safe conduct of the research; or
   - Any other factor which would warrant review of the proposed changes by the convened IRB.

4. **What is a Specific Finding?**

   Specific findings are the **specific regulatory criteria** that must be addressed for the IRB to make regulatory determinations.

   IRB Forms mirror regulations by asking for information to address each criteria that must be met for the IRB to make a specific finding.

   Examples of IRB specific findings and select regulatory criteria:

   - **Waiver or Alteration of Informed Consen**t – five waiver criteria
     Research involving Deception – Apply same five criteria since Altering Informed Consent and see criteria in deception guidance.
   - **Waiver of Documentation of Informed Consent** – waives requirement for signed document for sensitive research; minimal risk research where signed document not necessary; or populations where signature is not culturally appropriate
   - **Medical Devices –**Exempt from IDE requirements; Significant Risk/Nonsignificant Risk determination by convened board
   - **Pregnant Women, Fetuses and Neonates** – categorize potential risk and benefit to pregnant woman and the fetus which determines associated informed consent requirements
   - **Prisoners** – categorize prisoner involvement in study and justification of six additional criteria
   - **Children** –categorize potential risk and benefit to child which determines associated informed consent requirements and safeguards
   - **Wards of State** – may be included in research for certain risk/benefit categories some of which require appointment of an advocate

5. **How does the IRB determine whether convened IRB requested revisions should be designated as minor (vote #2) or major (vote # 3 or 4)?**

   Minor Vote 2: A vote of #2 at a convened meeting indicates that the IRB has given the individual chairing the meeting the authority to approve minor revisions which do not involve substantive issues.

   The types of revisions that can be approved by expedited review must be:

   - **directive** (specific changes or revisions requested of the investigator to secure approval) or
   - **non-substantive** (a change in which the judgment of the IRB reviewer, makes no substantial alteration in risks to subjects, selection of subjects, informed consent process, informed consent documentation, safety and monitoring or subjects' privacy or data confidentiality.

   Examples of Directive revisions that may be considered minor:

   - Changes in study research personnel;
   - Adding a blood draw (specified amount and purpose) to a research study;
   - Changes to improve the clarity of statements or to correct typographical errors without altering the content or intent of the statement (e.g. minor changes in the consent form).

   Major Vote 3 or 4: When the convened IRB requests **substantive (major)** clarifications or revisions (i.e. vote # 3 or 4) directly relevant to the regulatory determinations required by the IRB or does not have the information needed to determine whether the regulatory criteria are met, the protocol revisions must be deferred to the convened IRB for review and approval. Review of requested revisions by the convened IRB MUST occur if revisions are substantive and non-directive.

   Examples of Substantive revisions that request clarifications or information:

   - Clarify whether participants will be offered counseling services at the end of the study.
   - Describe protections in place for protecting rights of minor subjects.
   - Provide additional information regarding study design or endpoints.

6. **How does the IRB evaluate the investigator's plan for managing information that could affect the subject's willingness to continue participation?**

   IRB forms (CR, UP/AE) prompt the reviewer to consider significant new findings that might relate to the subject's willingness to continue participation.

   Notification vs. re-consent:

   The reviewer documents if the PI's proposal for communicating the information is appropriate and if not, describes revisions needed. The IRB evaluates the significance of the information in determining what course of action is appropriate **(notification or re-consent)**. Possible investigator actions include, but are not limited to: revising the consent document, re-consenting active subjects; notification to applicable subjects (past, current) with new information; suspending enrollment pending additional information, etc. See Reconsent or Notification Guidance.

Exemption Reviews

1. **Who has authority at UK to make exemption determinations?**

   The IRB has the authority to make exemption determinations (not investigators). Additional resources provide guidance regarding issues to address in determining when studies are exempt from regulations.

   Established policies and procedures govern reviewer conflict of interest in exempt review. The reviewer signature page prompts consideration of conflict of interest just prior to the signature.

Expedited Review Procedures

1. **Who can conduct expedited review?**

   IRB chairperson or one or more experienced and trained members.

   The expedited reviewer considers same approval criteria as full board. Research must be minimal risk and all procedures fit one or more expedited categories.

2. **Under what circumstances can the IRB utilize expedited procedures to review a proposed change to previously approved research?**

   The IRB can use expedited procedures to review Minor Modifications. A Minor Modification is one which, in the judgment of the IRB reviewer, makes **no substantial** alteration in:

   - The level of risk to subjects;
   - The research design or methodology;
   - The subject population;
   - The qualifications of the research team;
   - The facilities available to support the safe conduct of the research;
   - Any other factor which would warrant review of the proposed changes by the convened IRB.

Risk Assessment and Safety Evaluation

1. **What are the types of risk the IRB should consider?**

   The IRB should consider a wide range of categories regarding types of risks. For example, **risks can be physical, psychological, social, economic, legal or unknown.**

   Risks can apply to **individuals or may apply to classes of participants** (e.g., research on alcoholism in Native Americans).

   IRB reviewers should be diligent to focus only on the risks associated with the protocol that are **directly related to the research,** (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

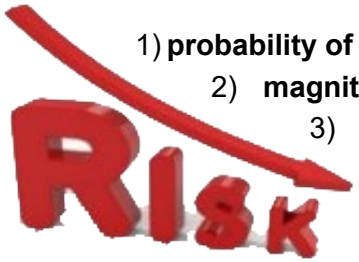
   The IRB should concentrate on the **immediate or reasonably foreseeable risks** of the research rather than the risks associated with the long-term outcome or consequences of applying the knowledge gained from the research.

   During review of a proposal, the IRB may refer to a document providing guidance on Assessing the Research Risk. See the PDF document: https://www.research.uky.edu/uploads/ori-d80000-uk-assessing-research-risk-pdf.

2. **What factors are considered when interpreting Minimal Risk?**

   The IRB considers probability or magnitude of harm from the research, relative to the general (healthy) population.

   1) **probability of harm**;
   2) **magnitude of harm**.
   3) **efforts to minimize risks**



3. How does the IRB determine whether the risks are reasonable in relation to the potential benefits?

The IRB first identifies potential risks. The IRB considers both probability and magnitude of harm and discomfort associated with the risk.

The IRB then identifies potential benefit.

The IRB then assesses whether risks to participants are **reasonable** in relation to the anticipated benefits to participants and importance of knowledge expected to result.

The benefits of a study do not negate or alter the level risk.

4. What outcomes may be impacted by risk classification?

The risk classification may influence many factors including but not limited to:

- the mode of review (expedited vs. full board);
- whether or not a protocol can be approved by the IRB;
- the need for a Certificate of Confidentiality;
- additional protections such as assigning an independent monitor for Department of Defense supported research;
- need for a data and safety monitoring plan;
- the frequency of review; and
- consent requirements (one of the criteria for waiver is “minimal risk”).

5. What is the UK IRB’s criteria for requiring a data and safety monitoring plan (DSMP)?

The IRB requires review and approval of data and safety monitoring plans (DSMP) for:

- Greater than minimal risk research; **or**
- NIH funded clinical investigations; **or**
- FDA regulated clinical investigations

6. What is considered in evaluating a data and safety monitoring plan?

The Criteria for Approval Checklist includes the following questions to consider when evaluating whether the data and safety monitoring is adequate:

- Is the proposed plan commensurate with the nature, size, and complexity of the research as well as the degree of risk involved?
- Does proposal include procedures for promptly detecting harm and mitigating potential injuries?
- What safety information will be collected? How will safety information be collected (e.g. at study visits, by monthly telephone calls, etc.)?
- What data will be monitored and who will monitor the data?
- What is the frequency of review or analysis of cumulative safety data to determine whether harm is occurring?
- Are there procedures for ensuring appropriate reporting of findings to the IRB?
- Are there any conditions or criteria that could trigger an immediate suspension/ termination of the research and if so are their procedures for reporting the suspension/ termination to the appropriate entities?
- Is establishment of an independent individual or data and safety monitoring board (DSMB) warranted? If so, is there a plan for providing DSMB reports, (routine and urgent), to the IRB?

7. **When must the IRB approve the appointment of a research monitor?**

   The IRB approves the PI's selection of a research monitor for greater than minimal risk research supported by the Department of Defense (DoD).

Noncompliance, Suspension or Termination of Research

1. **How does the IRB decide non-compliance, serious or continuing non-compliance?**

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human research. Noncompliance with IRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their rights and welfare.

Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious noncompliance is a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or

Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

2. **What determination does the IRB make when presented with a case of noncompliance that violates regulations, institutional policies or procedures applicable to human research?**

   The IRB decides whether event was **"Serious" or "Continuing" noncompliance**.

3. **What is the difference between suspension and termination?**

   A **suspension** - temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

   The IRB may suspend a study based on safety concerns (e.g., allow time to assess an unanticipated Serious Adverse Event) or compliance related (allow time for PI to implement corrective action for serious or continuing non-compliance).

   A **termination** -permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

   When a suspension or termination involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal (e.g., transfer to another investigator, clinical care).

4. **What is the IRB's purview in terms of suspending or terminating protocols?**

   The convened IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of human subjects.

   The IRB Chair or designee has the authority to request that the IRB suspend approval when the continuation of the research may adversely affect the rights and welfare of research subjects or when the

IRB needs additional information to ensure that the rights and welfare of subjects are protected and there is insufficient time to have the convened IRB review the situation.

Investigator Reporting Requirements & Unanticipated Problems Involving Risk

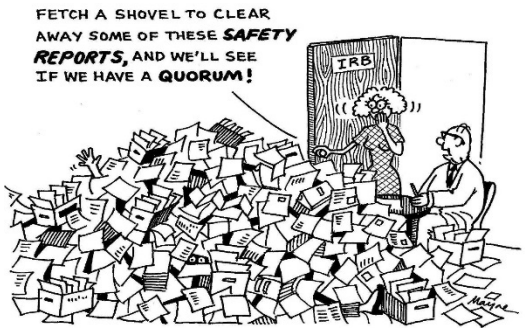
1. **What events/issues do investigators report to the IRB?**
   - UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS
   - VIOLATIONS – any change (deviation or exception) which occurred WITHOUT prior IRB review and approval
   - PROTOCOL NON-COMPLIANCE, SUSPENSION, OR TERMINATION
   - DATA AND SAFETY MONITORING REPORTS
   - FOOD AND DRUG ADMINISTRATION CORRESPONDENCE
   - UNRESOLVED SUBJECT COMPLAINT that requires IRB involvement
   - SUBJECT INCARCERATION
   - AUDIT, INSPECTION, OR INQURY BY A FEDERAL OR EXTERNAL AGENCY

2. **What unanticipated problems or adverse events are investigators required to PROMPTLY report to the IRB?**

   Prompt reporting is only required for **unanticipated problems involving risks to subjects or others (UPIRSO), Research-Related Deaths**, Other events or problems per the investigators judgement, warrant prompt review.

   Both the Food and Drug Administration (FDA) and Office for Human Research Protection (OHRP) have issued policies to deter over-reporting.

   - *Uninformative individual safety reports places a tremendous burden on the system without accompanying benefit.*
   - *Final FDA rule reduced the current number of uninformative individual safety reports,* enhancing reporting of meaningful, interpretable information.



3. **How does the UK IRB define an unanticipated problem involving risk to subjects and others (UPIRSO)?**

Unanticipated problem involving risk to subjects or others are any unforeseen or unexpected event or experience that adversely affects the rights, safety, or welfare of subjects or others (which is not described in the general investigational plan or elsewhere in the current application or with the current investigator brochure, or in the consent document). UPIRSO's involve or suggest new or increased risk that is unanticipated and related and serious.

The event or experience could involve physical harm/risk, social harm/risk, psychological harm/risk or legal harm/risk.

The experience could also involve events not previously identified in severity or degree of incidence.

4. Why are there so few events or problems that meet the threshold of UPIRSO?

Most adverse events are not unanticipated problems because they were anticipated/expected/or listed in the consent; were unrelated to participation in the research; or were not serious or did not suggest that research involves greater risk.

Generally, external safety reports are uninterpretable unless accompanied by a sponsor evaluation of risk altering risk-benefit ratio or resulting in changes in protocol documents, the monitoring process or a corrective action.

IRB Reporting Requirements

1. What are the primary IRB reporting requirements?

The IRB/ORI notifies appropriate officials (institutional official(s), sponsor, coordinating center, accrediting agency, and the appropriate federal regulatory agency) when human subjects research falls under the purview of a federal regulatory agency and one or more of the following occurs:

2. What does the ORI/IRB promptly report to AAHRPP?

ORI staff report within 24 hours of becoming aware of:

- Any negative actions taken by a government oversight office including but not limited to OHRP Determination Letters, FDA Warning Letters, and FDA restrictions placed on IRBs or Investigators;
- Any lawsuits (i.e., litigation, arbitration, or settlements initiated) related to human subject research protections; or
- Press coverage (including but not limited to radio, TV, newspaper, online publications) of negative nature regarding the UK HRPP.

Vulnerable Populations

1. How does the IRB evaluate whether appropriate provisions are in place for research involving vulnerable populations?

The investigator describes provisions in the IRB Application.

Policies and Guidance provide protections and safeguards.

- Adults with Impaired Consent Capacity Policy
- UK IRB Policy on Children in Research
- Protection of Human Subjects in Research Involving HIV Testing
- Summary on Prisoners Regulations – OHRP Video Series Prisoner Review
- Guidance for Enrolling Students as Research Subjects
- Guidance for Enrolling K-12 Students as Research Subjects
- Research Involving Economically or Educationally Disadvantaged Persons

2. Provide examples of safeguards the IRB might require for vulnerable subjects.

- Enhanced process to enable those with limited decision-making ability to assent or identify behaviors indicating dissent.
- Respectful recruitment methods – prohibit cold calls; consider privacy expectations
- Require third party recruitment and enrollment to minimize undue influence
- Employ a subject advocate
- Educate Legally Authorized Representatives (LAR brochure) to consider substituted judgement and best interest.
- Fair inducements/payments

3. What must the IRB consider when applying Subpart D regulations to FDA regulated pediatric research involving a placebo arm?

FDA has indicated that administration of a placebo would not meet Category 2, (research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects 21 CFR 50.52), because it would not offer a prospect of direct benefit.

Placebo-controlled pediatric clinical trials should be categorized under either Category 1, 3, or 4. Should the research fall under Category 4, a report must be sent to the applicable federal agency for review and the IRB may not independently approve the research.

4. What does the IRB consider when research involves individuals who have impaired decision-making capacity?

The IRB applies the – UK impaired consent capacity policy, and web-based interactive IRB Form T to determine assessment approaches and safeguards that are tailored to the:

1) study population;
2) level of study risk;
3) potential for fluctuations in impairment from recovery or worsening of conditions.

   and

4) safeguards and enhancements to the consent process to enable individuals who otherwise have limitations, to make competent decisions. Consent enhancements include adult assent, LAR information pamphlet*, methods for assessing dissent, study overview summaries.

*ORI provides pamphlets, **Advice to Legally Authorized Representatives of Adult Participants in Research,** for use in educating LARs regarding their special role and approaches to making decisions on behalf of participant (i.e., substituted judgment and best interest).

5. What concerns should the IRB consider when a study involves economically or educationally disadvantaged populations?

Economically or educationally disadvantaged persons may be subject to undue influence in participating in research due to limited understanding and/or unfair level of benefit in exchange for study participation (perception of free treatment, access to treatment, or compensation).

For the inclusion of economically or educationally disadvantaged persons, the benefits must not be so great that the subjects disregard the risks. Alternatively, the benefits of participation in comparison to the risk, must not be so minimal such that only those who are economically or educationally disadvantaged want to participate. Studies should not be skewed toward either extreme.

The Research Involving Economically or Educationally Disadvantaged Persons addresses the following concepts:

- Subjects enrolling in research without fully understanding study risks;
- Rewards/services or compensation that is unduly influential; and
- Unfair benefit in exchange for participation.

Informed Consent

1. How does the IRB evaluate the informed consent?

Document:

UK ORI has developed a Consent Checklist of general requirements; required elements; additional elements; FDA-specific and sponsor-specific items.

The IRB provides a variety of informed consent templates (English and Spanish) on the "Informed Consent" webpage and in E-IRB.

Process:

The research description asks for detailed consent procedures including who, where, time allotted, steps to minimize undue influence, method to document and provisions for special populations.

E-IRB PROVIDES LINKS TO THE INFORMED CONSENT REQUIREMENT CHECKLIST

2. What are the new informed consent requirements of the revised common rule?

- Concise format and organization to facilitate understanding
- Reasonable person standard
- Key Information first in form and process
- One New Basic Element:
  1) whether information or specimens will be deidentified and shared for future use
- Three New Additional Elements:
  1) whole genome sequencing;
  2) return of clinically relevant results;
  3) commercial profit
- Posting a consent document for federally-funded clinical trials.
- E-signature allowed

- Exception allowing investigators to access stored information or specimens to screen, recruit or determine eligibility (exception so no waiver required)
- Exempt categories 7 & 8 using broad consent – UK DOES NOT USE THESE
- Additional waiver criteria – for use of information or specimens with identifiers
- Additional waiver of documentation option – for not culturally appropriate to sign documents

3. What is the legal age for an adult in your state?

18 in Kentucky. If research is proposed in other states the investigator is asked on Form W to provide state age of majority and definition of legally authorized representative.

4. Who does the IRB require sign informed consent documents?

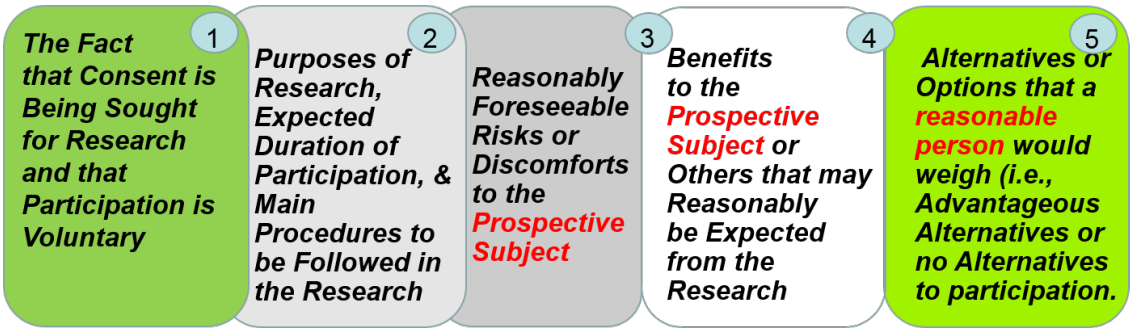
IRB policy requires the research participant (or their legal representative) to sign and date the informed consent form. The authorized study personnel conducting the consent process prints his/her name and dates the form. Investigator signatures are optional.

5. What is and is not appropriate as Key Information?

Key Information:	
ø Is Not a summary of full protocol (like an abstract)	✓ Is about a page or less
ø Does not need to include all required elements	✓ Is presented first vs. being dispersed in the document
ø Doesn't have to look identical to our template	✓ Should include the information that is most crucial to a participant's decision whether or not to participate
ø typically does not include exclusions unless the exclusion involves restrictions that would affect someone's decision to participate	✓ May or may not be risks & benefits; could be other pros and cons that a prospective participant would weigh

6. What may be included in Key Information?

Although not defined in the Common Rule regulation, Key Information is described in the preamble to include:



Key Information Samples for Simulated Studies are available on the Sample Applications and Protocol Development Resources webpage.

7. What are the language requirements for consent processes and forms in your organization?

If recruiting non-English speaking subjects, consent document must be translated in the subject's native language. The IRB provides a Spanish translation of informed consent templates. ORI/IRB obtains consultation to verify translation and cultural appropriateness of consent documents. The facility or IRB may have interpreter requirements for the process. Policies allow use of a short form but it is rarely used.

8. What should the IRB consider when reviewing a deception protocol?

To approve a deception study, the IRB must apply waiver of consent process. Considerations may include whether the deception is essential to the study to provide valid data; justification of importance of study; potential risks; adequate and appropriate debriefing; and necessary safeguards such as counseling. NEW – Debriefing and Permission to Use Data Form

9. How is informed consent waiver handled in research supported by the Department of Defense (DoD)?

Waiver of informed consent is prohibited for DoD supported research involving an intervention or interaction humans as Experimental Subjects, for Classified Research or for Planned Emergency research unless DoD has issued a secretarial waiver. The UK DoD Checklist provides requirements for reviewing DoD supported research.

10. Under what conditions can the IRB waive or alter informed consent for research such as medical record reviews or deception research?

Only under certain conditions can the IRB waive the requirement for the informed consent or allow alterations in the process where one or more of the required elements are absent (e.g., research employing deception to eliminate bias).

The IRB may waive the requirement for informed consent if it finds and documents that the research meets the following conditions:

a) no more than minimal risk involved;

b) rights and welfare of subjects not adversely affected;

c) the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

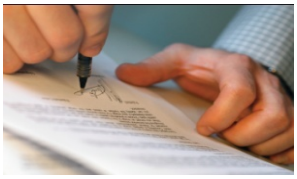
d) research COULD NOT be practicably done without the waiver or alteration; and

e) when possible, subject is provided with additional pertinent information after participation.

NOTE: FDA NOW ALLOWS WAIVER OR ALTERATION FOR MINIMAL RISK RESEARCH USING SAME CRITERIA

11. Under what conditions can the IRB waive documentation of informed consent?

1) The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).



2) The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).
3) Involves a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk to the subject and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Only under certain conditions can the IRB waive the requirements for documentation of informed consent. NOTE: there is no equivalent HIPAA mechanism to waive documentation.

FDA Regulated Research

1. For FDA regulated research, how does the IRB assess the investigator's qualifications, research site adequacy, and plan for control of investigational products?

- In performing scientific review, the Department Chair attest to appropriateness of personnel qualifications, equipment and facilities.
- The IRB application includes questions regarding staff, space, and equipment and qualifications. The drug and device section includes specific questions regarding experience and qualifications to administer an FDA-regulated test article.
- Sponsor-investigators are required to complete an online CITI Good Clinical Practice (GCP) course which covers both investigator and sponsor responsibilities for drug or device research.
- Should UK serve as IRB of record for FDA regulated research conducted by a non-UK investigator/institution, the non-UK institution attests to, or provides verification of, site's adequacy to execute the clinical protocol requirements (e.g., equipment, emergency/specialized care, test article security/accountability, etc.).

2. When a study involves a drug, what process does the IRB follow to make sure that the drug either has an IND number or meets the criteria to be exempt from an IND?

Investigators conducting clinical investigations with drugs or products regulated as drugs (biologics, select dietary supplements) complete the drug section of the IRB application. The section includes the IND number and holder if applicable (ORI verify the number).

Investigators provide details about the product, investigational plan, and approval status in the drug attachment.

- Meets criteria for exemption from IND requirements; or
- Is subject to IND requirements.

The drug form attachment provides links to the FDA criteria for IND Exempt categories.

For studies involving FDA approved drugs, the investigator must indicate if each criterion for exemption is met. Investigators are prompted to attach applicable supporting correspondence from FDA or commercial sponsors.

- The IRB may consult guidance on input from ORI staff with FDA expertise.
- If unsure, the IRB requires the PI or ORI to contact the FDA for a ruling.

The following flow chart illustrates the process.

A Drug is "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body.

A biologic is a virus, toxin, vaccine, blood, blood derivative, protein, gene therapy, growth factors, cytokines, monoclonal antibodies, and other organic compounds used to prevent, treat, or cure disease.

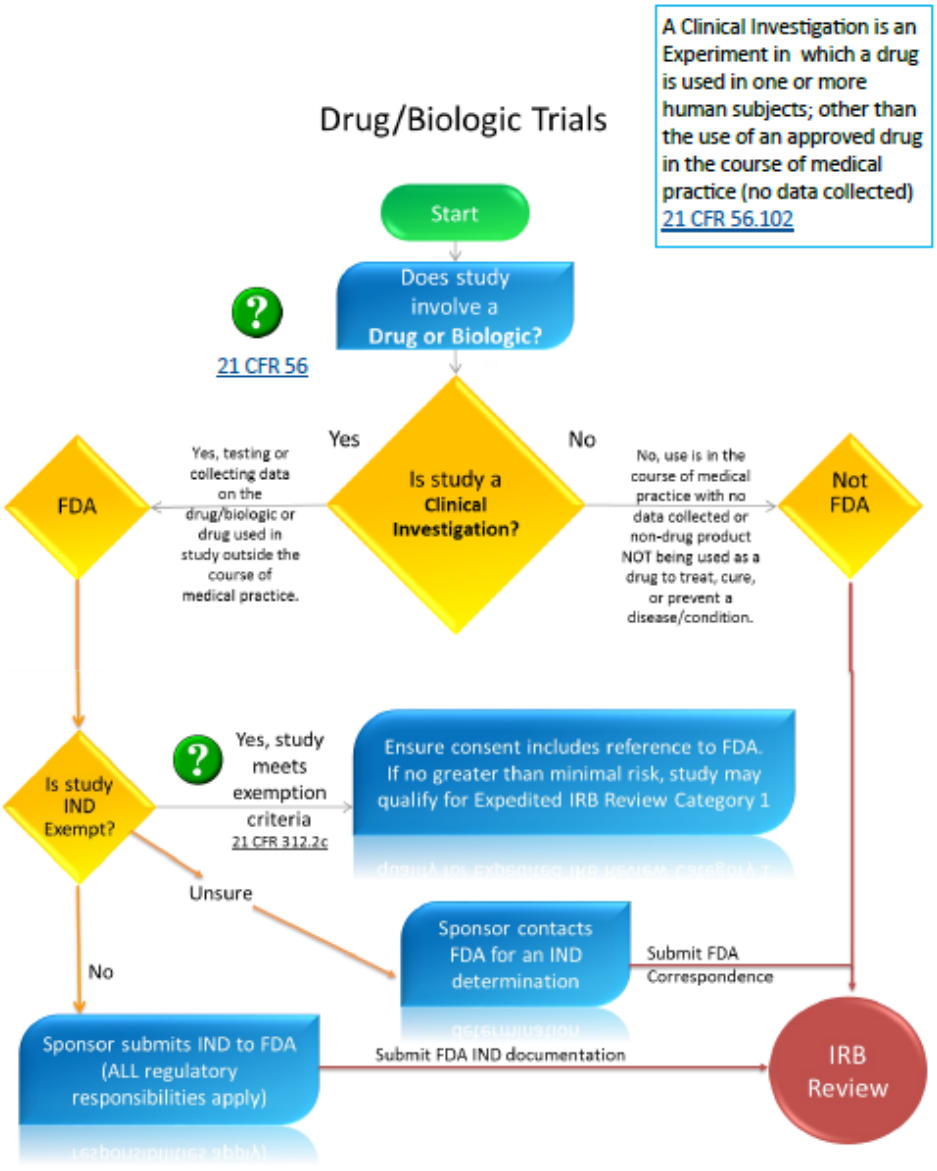
Examples of IND Exempt Trials

Unapproved use of an approved drug if all criteria met:
**Lawfully marketed in US;*
**Not in support of new indication*
**Not to change label or marketing*
**Does not involve route of administration, dose, population that significantly increases risk or decreases tolerability*
**has IRB approval & informed consent & not done for promotion.*

Dietary Supplement if study designed only to reduce risk of a disease; evaluate structure or function of the body; support a new or expanded health claim, and EXCLUDES individuals less than 12 months old, those with altered immune systems, or serious or life-threatening medical conditions.

FDA IND Exempt Guidance

Dietary Supplement FAQ
Studies Involving E-Cigarettes



3. Can an Investigational Brochure (IB) be used to validate an IND number?

No, the IB may represent many INDs. ORI validate using the sponsor protocol or correspondence from the sponsor and/or FDA.

4. When a study involves a device, what process does the IRB follow to make sure that the device either has an IDE number, is nonsignificant risk, or meets the criteria to be exempt from IDE requirements?

Investigators conducting clinical investigations with medical devices, complete the device section of the IRB application. The section includes the IDE/HDE number and holder if applicable (ORI verify the number).

Investigators provide details about the product and investigational plan in the Device Attachment. The attachment includes criteria and categories to designate the device study as:

- Exempt from IDE requirements;
- A nonsignificant risk (NSR) device study; or
- A significant risk (SR) device study requiring an Investigational Device Exemption (IDE).

Only the convened IRB may make an SR/NSR determination. ORI staff document the SR/NSR determination in the meeting minutes. The IRB may request that the PI consult with the FDA as appropriate. If FDA provides a determination, it is considered final and the IRB does not duplicate the effort.

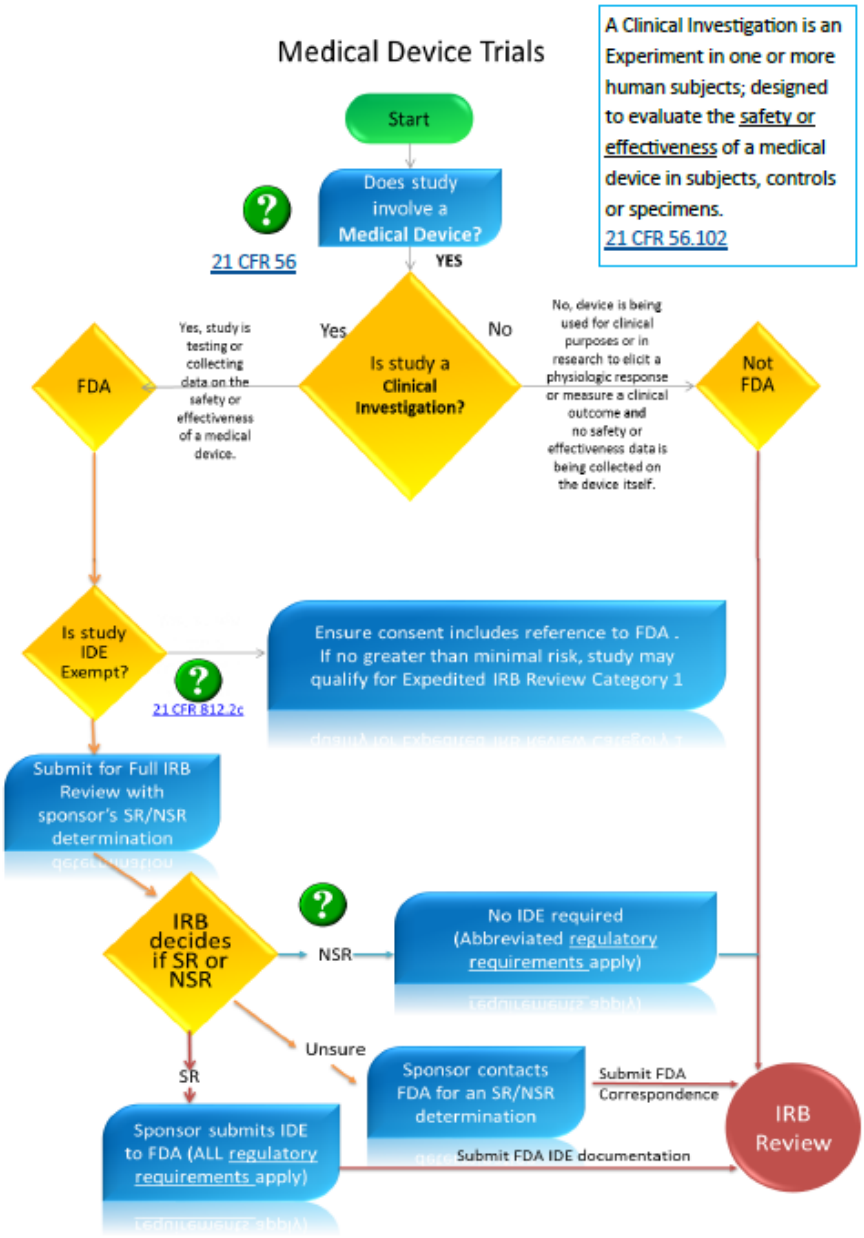
The following flow chart illustrates the process.

A Medical Device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article, including any component, part, or accessory, & is—
• intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man, or
• intended to affect the structure or any function of the body of man
• and does not achieve its primary intended purposes through chemical action or being metabolized. See FDA FAQ

Examples of IDE Exempt Trials *must meet all applicable conditions*
- Study of device used in accord with FDA approved labeling and indications* and no intent to report to FDA in support of new indication or label change.
- An In-vitro device that meets IDE exclusion criteria.
- Mobile Medical App equivalent to examples for which FDA intends to exercise enforcement discretion.

In-Vitro Device Guidance FAQ
Digital Health/Mobile Medical App

The convened IRB considers device AS USED IN STUDY when making SR/NSR determination. The investigator should provide manufacturing information, labeling or other material describing FDA-approved indications.



5. **What type of device studies are reviewed using Expedited review procedures?**

Only minimal risk studies that meet expedited requirements and Expedited Category 1:

ii. an IDE is not required; or

iii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling (approved device/approved use)**.**

All other device studies would require review and significant risk/nonsignificant risk determination by the convened IRB.

6. **What is the process for a Single-Patient Emergency Use of an investigational product?**

Notification of IRB Chair:

- The UK Emergency Use SOP is more stringent than the FDA requirements as it requires notification of the IRB Chair, Vice Chair, or physician IRB member prior to emergency use to allow confirmation that the use does appear to meet emergency use criteria (as opposed to compassionate use).
- This also serves to initiate tracking to ensure the investigator files a report within the five-day time-frame.
- If time is not sufficient to obtain assessment by the IRB chair or designee, the PI proceeds with the use and reports to the IRB writing within five working days of use.

Convened IRB Review of Five-Day Report:

- PI submits Five Day Report including the following which is reviewed at a convened IRB meeting.
  - A brief description of the life-threatening situation;
  - Justification for use of the test article;
  - Signed consent form or justification for administration without informed consent;
  - Statement of review and evaluation of the situation by a physician who is not participating in the clinical investigation (if administered without informed consent);
  - Completed General Information Sheet (unless supplied earlier); and
  - A description of outcome of administration.

7. **What are examples of language or information that must be included in the informed consent document/process for FDA regulated research?**

For applicable FDA-regulated clinical trials, a statement to inform subjects the clinical trial will be registered with a national **clinical trial registry data bank** (clinicaltrials.gov).

For FDA-regulated clinical trials, a statement to inform subjects that if he/she should choose to **withdraw early** from the study, the data collected to the point of withdrawal remains in the study database and may not be removed.

Also include FDA in applicable sections of consent document (e.g., **purpose** is to evaluate an FDA regulated product, **results** of study will be shared with FDA, description of intervention with **FDA regulated product**, officials of **FDA may look at or copy portions of records** that identify the subject)

Community Based Participatory Research (CBPR)

1. **What are considerations when reviewing CBPR)?**

A. How research involves community members in the design and implementation of the study!

B. How results will be shared with the community.

C. Whether qualitative research protocols are written to include flexibility in operational procedures or semi-structured interview allowing flexibility within defined parameters. Investigators are encouraged to describe operational procedures that are general or include a range of procedures to allow flexibility, while including enough details to allow the IRB to apply the federal criteria for approval.

2. What resources are available to Community Engaged or Community Based Participatory Researchers?

ORI provides a frequently asked questions (FAQs) guide to assist researchers in the design and implement research in the community and facilitate Institutional Review Boards' review of CER/CBPR.

CBPR investigators may work with ORI education, to propose use of non-traditional, CBPR-focused human subject protection training for community partners.

The UK **CCTS Community Engagement and Research** offers resources, facilities, consultation, training, and funding opportunities for community engaged research.

Communication and outreach to current and prospective research participants

1. Who provides outreach to educate the public and potential participants?

The Participant Recruitment/Marketing core of the Center for Clinical and Translational Science (CCTS) works with UK Healthcare, UK Marketing, ORI, and research investigators to provide education, outreach, and research opportunities to the public.

The CCTS Participant Website provides several mechanisms for the public to learn about research participation including videos, outreach events, kiosks, and databases.

The ORI Participant Website provides additional participant education links as well as contact information for subject concerns, suggestions or questions.

The ORI website provides:

- Information about participating in research;
- Clinical trial considerations;
- Material for Parents and Children;
- Information in Spanish; and
- Descriptions of an IRB and What is meant by Accreditation.

2. Who would a prospective subject call with a complaint regarding a perceived invasion of privacy?

The ORI Director serves as the primary contact for current, prospective, or past research participants. Each IRB approved informed consent document as well as CCTS outreach materials include the ORI 's toll-free phone number (1-866-400-9428) as a subject's primary contact point to obtain information, offer input or discuss problems, concerns, or questions about research participant rights.

3. What about international or non-English speaking subject complaints?

Contacts listed in the informed consent documents for international or non-English speaking populations are determined on a case-by-case basis.