IRB Review

A compilation of 'need to know' updates for UK Institutional Review Board (IRB) members, investigators and others involved in human subject research

UK UNIVERSITY OF KENTUCKY Office of Research Integrity

NEW FAQ on Return of Research Results or Incidental Findings

The Office of Research Integrity (ORI) announces the release of the UK Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings.

About a year ago the ORI and the Center for Clinical and Translational Sciences (CCTS) began a joint initiative to assemble a committee charged with the development of an IRB framework for the return of incidental findings and research results. The committee members filled multiple roles and represented various stakeholder perspectives, including the IRB, regulatory/administration, clinical and translational research, pathology, laboratory administration, clinical genetics, clinical bioethics, repository participation, and pediatric dentistry. The group conducted an extensive review of literature and met approximately twice a month to discuss the ethical, legal, social, and regulatory issues raised within the context of returning individual research results and incidental findings.

This is a complex and challenging topic with diverse views among federal agencies, funding organizations, and the general public. In the absence of standardized regulatory guidance, the FAQ presents expectations regarding ethical obligations within the context of research. The FAQ is most applicable to research involving procedures such as genetic testing or high-density imaging, which may generate results or findings of significant importance to the health of the participant or their family. It includes criteria a researcher can apply to determine whether or not a result or finding should be offered to a research participant. Options for informing participants regarding the potential, risks, benefits, and implications of receiving such results are also discussed.

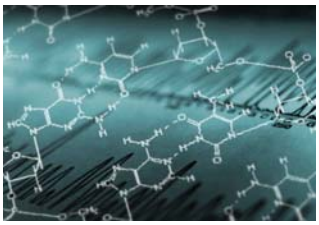
The IRB adopted the committee recommendation to release the FAQ in November and the ORI begin making changes to operationalize the guidance such as adding applicable questions to the Research Description (Medical Form B) to prompt investigators to consider and propose a plan where applicable. In addition to the FAQ, a single-subject, result-specific consent is available to customize and use in the event that a result meets all criteria to return and the consent initially obtained did not offer the participant an option to receive or refuse potential results or findings.

Like many new endeavors, the goal is to provide an initial framework that will likely evolve in practice and in theory, based on practical lessons learned, advances in technology, and eventual consensus standards.

The FAQ and Sample Single-Subject Consent are available on the ORI Survival Handbook.

- Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings [PDF]
- Sample Single-Subject Consent to Receive or Refuse Result or Incidental Finding - [PDF]

Plans to host an education session on this topic and initiative are currently in the works.



The ORI and CCTS thank & acknowledge the working group who contributed to this project:

Mike Cibull, MD, Kristy Deep, MD, Jim Hartsfield, DMD, PhD, Dennis Karounos, MD, Ada Sue Selwitz, MA, Belinda Smith, MS, CCRC, and Juan Yepes, DDS, MD

Biobanking Informed Consent Resources

Informed consent is one of the most important ethical issues involved in banking of biological material and establishing research repositories. However depending on the design, protections, and practices of a repository, the level and type of informed consent that is appropriate varies greatly. Ultimately, the future research conducted by investigators or recipient researchers who access material from a repository should be consistent with the uses described at the time of consent.

The UK Office of Research Integrity (ORI) has updated guidance and consent language to help investigators and organizations develop a process that fits the unique characteristics of the repository or banking study.

Because of the extensive variation in the design and operation of banks and research repositories, a "*one size fits all*" template is not feasible.

The ***Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future*** **Use [PDF]** presents issues for consideration, sample template language, and optional approaches for the consent process.

The ***Sample Consent to Participate in a Research Repository or Individual Study Banking Material for Future Use*** **[WORD]** is a pre-fabricated version of the consent language from the Issues document. Investigators may copy or customize applicable portions of the sample template which includes elements of informed consent, a section for banking sub-studies, and authorization language if the repository involves use and disclosure of protected health information.

Office For Human Research Protections (OHRP) Clinical Research Conference – Cincinnati, OH – May 21, 2014

Registration is open for the OHRP dynamic Research Community Forum (RCF) that will be held on May 21, 2014 in Cincinnati, Ohio.

This exciting education one-day event is focused on ethical issues for protecting human subjects and some of the innovations on the research horizon.

The conference will be held at the Kingsgate Marriott Conference Center at the University of Cincinnati located at 151 Goodman Drive in Cincinnati, Ohio.

See full website brochure for registration and complete program details at:
www.cincinnatichildrens.org/service/c/clinical-trials/sponsors/ohrp-forum/default/

ORI IRB Form Updates

In addition to previously mentioned edits to the medical informed consent templates and research description to address return of research results and provide biobanking resources, the following form edits are effective immediately.

Medical Supervisor Signature removed on Unanticipated Problem/Adverse Event Forms

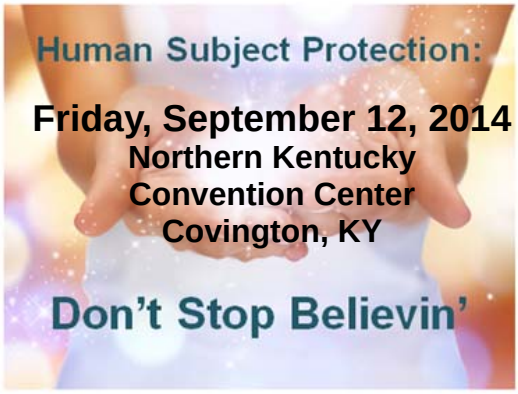
Previously the internal and external "Prompt Reporting Forms for Unanticipated Problems, Serious or Life-Threatening Events, and Related Anticipated and Unanticipated Deaths" have had a line for the signature of a "medical supervisor" if the clinical study PI is not an MD. In light of upcoming electronic changes and feedback received by reviewers and IBC representatives, the signature line has been eliminated. In its place, the IRB asks for confirmation that appropriate study personnel have reviewed and acknowledged the contents of the report. This signature requirement change is effective immediately. The new request is as follows:

> **For Clinical Studies where the Principal Investigator (PI) is not a physician:**
> *If this report is for a clinical study and the Principal Investigator (PI) is not a physician*, a sub-investigator who is licensed to recognize, diagnose, and treat adverse events (e.g., MD or DMD) must review this report, and you, the PI, must confirm that an MD/DMD sub-investigator has reviewed and acknowledges the contents of this report:
> Confirmed? o Yes o No

Study Personnel List Template – New Data to Collect

As you may be aware, Research Information Services (RIS) has been charged with developing a customized online IRB application. In anticipation of what this means in the future for researcher identification, log-ins, and tracking human research protection training, ORI has been asked to collect specific information for study personnel starting now. In particular, this adds to the data requested for non-UK affiliated study personnel (i.e., personnel without a LinkBlue account). ORI has revised the study personnel list template accordingly. We hope you can complete as much of the requested information as possible; this will improve the integrity of our data for the future. *Thank you in advance!*

Save the Date for the 16th Annual Human Subject Protection Conference!



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Conference Brochure Coming Soon!