HRP-309 | 7/31/2024

WORKSHEET: Ancillary Review Matrix

Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB’s review of a new study or a modification to an existing study.

* Ancillary reviews may be assigned by either the researcher or the IRB.
* The IRB typically assigns ancillary reviews during the pre-review of a submission.
* Once an ancillary review is triggered, researchers should work directly with those entities to ensure compliance.
* The ancillary review in Endeavor is intended to support compliance across multiple oversight groups and not replace review processes by other compliance groups.
* Ancillary reviews are not assigned by the IRB if a project does not meet the federal definition of Human Subject Research.

The impact of an ancillary review group’s approval on the IRB’s review process varies.

* Typically, final IRB approval is held until the ancillary group concludes their review.
* In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
* The IRB will not hold for the completion of ancillary reviews for studies that meet exempt criteria.
* Documentation of approval by an ancillary review group is provided to the researcher. The researcher is responsible for uploading that documentation in the “Supporting Documents” section of the Endeavor application to which it relates.
* In rare instances, either the ancillary review group or an IRB member may request deviations from the typical review path. An IRB member may recommend holding a submission until an ancillary approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending.
* Ancillary reviews that are required for IRB review/approval are not the same requirements for study activation. Study activation requirements are different and managed by Clinical Research Administration.

The table below highlights the ancillary review groups available and illustrates the typical impact an ancillary review has on IRB review. Please contact the IRB or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.[[1]](#endnote-2)

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| **Organization** | **Review Type** | **Ancillary Review Triggered by** | **Affected IRB Submission Types** | **Contact Info** | **How to Obtain Review** | **Impact on IRB Review**  (prior to, after, or parallel with) |
| Department Head/Chair | Ancillary - Mandatory | Mandatory for all protocols | All new protocol submissions | Various | Assign ancillary review during intake | Prior to |
| Certificate of Confidentiality | Ancillary | Protocols that require a Certificate of Confidentiality | Protocols that require a Certificate of Confidentiality | Niki Johnson | Assign ancillary review during intake | In parallel |
| MRI Safety Advisory Council | Ancillary | Protocols that involve magnetic resonance imaging (MRI) | Protocols that involve magnetic resonance imaging (MRI) | Tom Denney, Ph.D. & Ron Beyers, Ph.D. | Assign ancillary review during intake | In parallel |
| Institutional Biosafety Committee | Ancillary | Protocols that involve biospecimens, or involve other risks and safety concerns outside the scope of the IRB’s expertise, or mandated by the state (i.e., radiation) | Protocols involving biological specimens or radiation exposure (or other risks outside the IRB’s expertise) | David Acker | Assign ancillary review during intake | After approval for those requiring Alabama Department of Public Health approval (i.e., protocols involving radiation exposure); in parallel for all others |

1. If the requirement for an ancillary review differs for studies relying on an external IRB, indicate the differences in this table. [↑](#endnote-ref-2)