

Release 2.0

Amendment Processing Summary

Amendment processing will change with the implementation of Release 2.0. Prior to release 2.0, amendments were required to be processed through all of the committees that reviewed the original application, even if the changes are not relevant to that committee. After Release 2.0, non-IRB committees will only review changes that are relevant to them.

The chart below details what types of amendment changes non-IRB committees will now review.

| Committee Name  | Section Change          | Protocol change | Informed Consent Change |
|---|-------------------------|-----------------|-------------------------|
| PRC<br>(Protocol Review Committee)                            | 1-6, 3-2                | X               |                         |
| MCRU<br>(Michigan Institute for Clinical and Health Research) | 8-1, 42, 42-1           | X               | X                       |
| IDS<br>(Investigational Drug Service)                         | 1.2, 1.3, 8.1, 15, 15-1 | X               |                         |
| BEU<br>(Biomedical Engineering Department)                    | 16                      |                 |                         |
| IBC<br>(Institutional Biosafety Committee)                    | 23, 23-1, 23-2          | X               | X                       |
| MADRC<br>(Michigan Alzheimer’s Disease Research Center)       | 18-2, 43                | X               | X                       |
| RPC<br>(Radiation Policy Committee)                           | 21, 21.2                |                 |                         |
| SHUR<br>(Sub-committee on Human Use of Radiation)             | 21-1, 21-2, 21-3        |                 |                         |
| RDRC<br>(Radioactive Drug Research Committee)                 | 21-1, 21-2, 21-3        |                 |                         |
| TPC<br>(Tissue Procurement Core)                              | 18-1                    |                 |                         |
| COI MED<br>(Conflict of Interest MED)                         | COI                     |                 |                         |
| COI OVPR<br>(Conflict of Interest OVPR)                       | COI                     |                 |                         |