

Primary Reviewer Responsibilities

- Comparing the detailed grant application or industry protocol with the IRB application;
- Informing the full IRB of any discrepancies between the detailed protocol and the summary application materials;
- Determining whether the project involves a NIH multi-center clinical trial (e.g., cooperative group trial) and, if so, comparing the “Risks” and “Alternatives” section of the NIH-approved sample informed consent document with the UK proposed form to ensure that the NIH and UK sections of the consent are consistent;
- Ensuring that a Data and Safety Monitoring Plan (DSMP) exists IF research is greater than minimal risk or an NIH funded or FDA regulated clinical investigation;
- Reviewing the financial disclosure questions and alerting the IRB if a “yes” disclosure is made;
- Reviewing the other committee review/final approvals for consistency in human subjects protection measures;
- Checking the Signature Assurance sheet for appropriate signatures; and
- Conducting an in-depth review.