



Your CRO Partner for Success

YOUR FIRST CHOICE FOR QUALITY, COST-EFFECTIVE CREATION, REVIEW AND MAINTENANCE OF INFORMED CONSENTS



Informed consent creation, review, and approval of site IRB/IEC changes are important steps for site enrollment readiness and patient safety.

Our informed consent reviewers work with your protocol and requirements, regulatory agency guidelines, legal counsel, and sites to finalize consents. Potential subjects will have a consent that gives them the necessary information to make informed decisions regarding participation, while still meeting sponsor, site, and regulatory requirements.

“ Get the most out of your study and resources by partnering with BMA ”

Our goal is to provide world class support services that keep your projects on time, within budget and compliant to all regulatory authorities.



Creation, Review & Maintenance of Informed Consents

- FDA/CFR & ICH/GCP Adherence
- Creation of Template Consents
- Submission of Template & Revised Consents to Central IRB
- Negotiation with Site & Sponsor to Reach Final Consent
- Quality Check Process
- Review IRB Approved, Renewed, or Modified Consents
- Maintenance & Storage of IRB Approved Consents
- Review & Approval of Local IRB Required Changes
- Management of All Site-Initiated & Sponsor-Driven Consent Changes Throughout Trial

Contact us today to discuss your support needs.



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