Research Related Documents

1.0 Research Related Documents

A research related document is defined as any document used when conducting a study.

Research Related Documents include the following:
- Informed Consent Document(s)
- Children’s Assent Document(s)
- Advertisements, flyers, web postings, brochures, recruitment/information letters
- Screening/Telephone scripts
- Drug brochures
- Diaries, surveys, questionnaires
- Data collection forms
- Sponsor protocol

2.0 Submitting Documents at Initial Review

All research related documents defined above should be attached to the initial submission to the IRB.

3.0 Submitting Documents as Amendment/Modification

Any changes that are made to the approved documents must be submitted as an amendment (protocol revision) for IRB approval. This includes any revision to content and/or or creating additional research related documents.

4.0 Review by IRB

All documents that are submitted to the IRB are reviewed to assess compliance with FDA, DHHS, ICH, and institutional policies/regulations.

The following documents are stamped with an approval and expiration date:
- Informed Consent Document(s)
- Children’s Assent Document(s)

The following documents are stamped with only an approval date:
- Advertisements, flyers, web postings, brochures, recruitment/information letters
- Screening/Telephone scripts
- Diaries, surveys, questionnaires
- Data collection forms

5.0 Exceptions from Stamping

There are exceptions for certain types of documents in which an IRB stamp is not required. These documents include the following:
- Standardized questionnaires, scales, tests (REALM, SF12, QOL, etc.)
- Sponsor generated case report forms (CRFs), diaries, advertisements, etc.

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