

Common Research Institute Terminology

Brain: Internal documentation of the status of a study; includes all studies that are currently under investigation, who is working on them, and where in the process the study is in regards to the Good to Go email

CDA (Confidentiality Disclosure Agreement): An agreement between the sponsor and potential investigator that study information will remain confidential in order to receive information about the protocol

Check Request Form: Form completed by investigator/study coordinator to request a payment to be paid from a Research Institute account

Checklist: Hospital/pharmacy approval to conduct a study

CRA: Clinical Research Administration

CTA: Clinical Trials Administrator; main contact for study start up, responsible for IRB submissions and budget negotiations

CRA Database: Where studies are tracked

Executed Contract/Fully executed contract (FEC/FEK): A contract that has been signed by the investigator, sponsor, and Research Institute

Financial Disclosure Form: A form required by the FDA stating the financial interest or investment of investigators

“Good to Go”: An email to the PI and study coordinator to let them know the entire study start up process has been completed and they may begin to enroll patients

Grant Accounting Number: Number assigned to the project when it has been approved. This number is placed on the check request form when requesting monies from the account

HSC (IRB): Human Subjects Committee; responsible for approval of all study-related activities

IND (Investigational New Drug Application): An application to the FDA for drug approval of a new drug or a new indication

Investigational Pharmacy: Dispense, store, and keep accountability of study drugs

K: Contract

Common Research Institute Terminology

KUPI (Kansas University Physicians, Inc.): A clinical physician organization within the University of Kansas Medical Center

Ongoing Trial: A trial that has completed the study start-up process including a fully executed contract and HSC approval, as well as

Partially Executed Contract: A contract that has begun the routing process and has at least one signature

Pending Trial: A study that is in the set-up process

Principal Investigator (PI): The person in charge of the conduct of the study

Regulatory Documents: Documents required by every study to be submitted to the sponsor/FDA; includes 1572, financial disclosure forms, CV, licenses, etc.

RI: Research Institute

SPA: Sponsored Program Administration

Sub-Investigator: An investigator helping with a study under the Principal Investigator

Study Billing Number/Speedtype Number: The number assigned to a study for billing purposes

Continuing Review Form/Summary Progress Report (SPR): A form completed by the investigator yearly to either continue or discontinue the study with HSC. This form is a summary of the past year including subjects enrolled, subjects dropped and any serious adverse events that have been reported. It also includes changed made to the protocol. A current consent is submitted with this form to the HSC for review

Serious Adverse Event/Adverse Event: A problem in a study due to drug/device or procedure that affects study subjects negatively

1572: A contract between the PI and FDA stating who is involved in the trial, where it will be conducted, and which trial is being studied