# INTERNATIONAL CLINICAL RESEARCH ACADEMY

405 Ogilvy Avenue, suite #101, Montreal, QC, Canada, H3N 1M3

# DIPLOMA

This is to acknowledge that

## Safra Fairuz, CCRP

***successfully completed the Clinical Research Professionals (CRA/CRC) Certification Program***

Duration: 200 academic hours.Course outline:

- ♦ Pharmaceutical Industry Overview
- ♦ History of Clinical Trials Regulations
- ♦ Ethical Principles Clinical Research
- ♦ Medical Terminology and CT Glossary
- ♦ Overview Of Drug Regulatory Process
- ♦ International ICH GCP Guidelines
- ♦ FDA Title 21 CFR and 45 CFR 46
- ♦ Canadian Clinical Trial Regulations
- ♦ Phases of Clinical Trials & requirements
- ♦ Roles of Sponsor, Investigator, CRA, CRC
- ♦ Institutional Review Board IRB/IEC/REB
- ♦ Informed Consent, ICD Design
- ♦ Safety Monitoring, AE/SAE Reporting
- ♦ Study Design, Preparation, Start-up
- ♦ Protocol and Case Report Form Design
- ♦ Clinical Trials Conduct, CRA & CRC Tasks
- ♦ Subjects Recruitment and Retention
- ♦ Site Evaluation and Site Selection Visit
- ♦ Investigator Meeting & Site Initiation Visit
- ♦ Monitoring Efficiency, Site Monitoring Visit
- ♦ Clinical Trial Site Management Activities
- ♦ Study Termination, Site Close-Out Visit
- ♦ Data Management in Clinical Trials
- ♦ Preventing Errors, Fraud and Misconduct
- ♦ Audits and Inspections
- ♦ DSMB Data Safety Monitoring Board
- ♦ HIPAA Compliance Requirements
- ♦ Essential Documents in Clinical Trials
- ♦ EDC and Clinical Trial Management Systems
- ♦ PMN Pre-Market Notification FDA 510(K)
- ♦ PMA Medical Devices Pre-Market Approval
- ♦ IDE Investigational Device Exemptions
- ♦ Time Management and Work Organization

President: _____
Svetomir Krastev, MSc, CCRA

Clinical Research Training Center * Montreal *

Montreal, 7 March 2023

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