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Nota di contenuto	Section I. Pandemic Preparedness and Research Response: A Necessary New Field -- 1. Introduction -- 2. Clinical Research on Infectious Diseases -- 3. Guiding Principles for Emergency Research Response -- Section II. Norms for Emergency Research Response -- 4. Ethics of Pandemic Research -- 4.1. In Practice: Vaccine Efficacy and Safety Testing - An Ethical Case for Individual Randomization -- 4.2. In Practice: Research Ethics Committee Review in Public Health Emergencies -- 5. Health Emergency Research amid Global Inequities -- 6. Meeting Regulatory Criteria and Seeking Licensure -- 7. Research,

Sample, and Data Sharing During Outbreaks, Pandemics, and Beyond --
Section III. Preparedness for Emergency Research Response -- 8. Building Biomedical Research Capacity in Low- and Middle-Income Countries -- 9. Laboratory Needs for Research Response -- 10. Understanding How and Where Pathogens Emerge -- 11. Accelerating Diagnostic Innovation for Pandemic Control -- 12. Vaccine Candidates for Novel Pathogens.-12.1. In Focus: Novel Manufacturing Platforms for Pandemic Preparedness and Emergency Response -- 13. Accelerating Vaccine Development -- 14. Accelerating Development of Therapeutics for Preparedness, Response, and a More Secure World -- 14.1. In Practice: The RECOVERY Trial -- Section IV. Research Response -- 15. ACTIV: A U.S. Public-Private Partnership Responds to COVID-19 -- 15.1. In Practice: Leveraging an Integrated National Health System for Research Response -- 16. Challenges for Emergency Research Interventions in Fragile, Weak, and Failed Nation States -- 16.1. In Practice: Responding to an Infectious Disease Outbreak amid a Humanitarian Emergency -- 17. Integrating Clinical Research into Ebola Response: Liberia Case Study -- 17.1. In Practice: Integration of Clinical Research and Patient Care in the DRC PALM Ebola Therapeutics Trial -- 18. Good Participatory Practice. Social Mobilization, Communications, and Community Engagement -- 18.1. In Practice: Building Community Engagement for Clinical Research Response -- 18.2. In Practice: Adapting Social Analytics for Research Response -- 19. Understanding and Reporting the Natural History of an Infectious Disease -- 20. Turning Research Results into Clinical Practice Guidelines in Public Health Emergencies -- Section V. Methodology for Research Response -- 21. Epidemiological Research in the Setting of Outbreak Response -- 21.1. In Focus: The Impact and Mechanisms of Superspreading -- 22. Vaccine Trial Designs -- 22.1. In Focus: Ring Trial Design -- 23. Data and Safety Monitoring of Clinical Trials During Public Health Emergencies -- 23.1. In Practice: Monitoring the PALM Ebola Therapeutics Study in the Democratic Republic of the Congo -- 24. Mathematical Modeling for Emergency Response -- 25. Models in the COVID-19 Pandemic -- 25.1. Case Study: Modeling Fractional-Dose Emergency Vaccination Campaigns for Yellow Fever -- 26. Social Science Evidence for Outbreak and Pandemic Response -- Section VI. Governance, Institutions, and Partnerships -- 27. A Global Framework for Research Preparedness and Response -- 28. Financing Emergency Research Response during Infectious Disease Outbreaks -- 29. International Collaboration to Advance Research Preparedness and Response -- 30. Organizational Partnerships for Preparedness and Response to Emerging and Re-Emerging Infectious Diseases -- 30.1. In Focus: Research and Medical Humanitarian NGOs -- 30.2. In Practice: Building and Maintaining Preparedness for a Rapid Research Response in Indonesia -- Section VII. Research Operations -- 31. Operational Recommendations for Streamlining Emergency Research Responses to Pandemics -- 32. Launching a Clinical Research Operation -- 32.1. In Practice: Clinical Research Communications During an Outbreak -- 32.2. In Focus: Clinical Trial Insurance and Indemnification -- 33. Ethical Review of Research During an Emergency Response -- 33.1. In Practice: Ethical Review During Emergencies - The Liberian Experience -- 33.2. In Practice: Independent Monitoring of Emergency Response Clinical Trials -- 33.3. In Practice: Capacity Building for Research Ethics Review in Low- and Middle-Income Countries -- 34. Information and Communications Technology to Support Research Low-Resource Settings -- 35. Data Management in Emergency Response Research -- 36. Safety and Pharmacovigilance in Emergency Research Response -- 37. Supply and Logistics for Clinical Research in Low-Resource Settings

-- 38. Pharmaceutical Management -- 39. Cold Chain and Electrical Power for Emergency Research Response -- 40. Selecting and Opening a Clinical Research Site in a Low-Resource Setting -- 40.1. In Practice: Improving Patient Care in the Field - The CUBE Isolation Unit -- 41. Management of Security for Clinical Trials During Emergencies -- 42. Locally Hired Staff for Clinical Research Sites in Low-Resource Settings.

Sommario/riassunto

Robust global health security requires effective preparation for and response to emerging and re-emerging pathogens. The nascent field of emergency research response and preparedness is a crucial component in preventing and mitigating outbreaks, yet it is rife with critical scientific, ethical, and policy questions. How can local, national, and global systems collaborate across disciplines and political boundaries to protect health security? How can we conduct rigorous research in fragile or failed nation-states? What is needed for equitable distribution of vaccines and therapeutic medicines in short supply? How can we accelerate trials of vaccines and therapeutics during an emergency without compromising scientific rigor or ethical standards? How do we integrate communities and stakeholders into research preparedness and response? The editors bring decades of experience to their collaboration with renowned research scientists and health policy experts. Together they have crafted a compendium that proposes normative standards and offers practical guidance for preparedness and rapid research response. This pioneering, open access textbook presents principles and practices forged from experience in health emergencies – insights that illuminate a path forward for research response and preparedness. The goal is to stop outbreaks from becoming avoidable pandemics, and to mitigate illness, death, and social disruption if they cannot be stopped. Principles and Practice of Emergency Research Response merges historical understanding with insights into possible futures. It will serve as an indispensable compass for curtailing infectious disease threats through research, global health policy changes, and research capacity improvements where they are most needed. This book will be an ongoing reference for governments, health organizations, development agencies, researchers, policy experts, ethicists, and socialscientists. To facilitate focused and enhanced learning, it incorporates pedagogical tools such as abstracts, learning objectives, discussion questions, real-life examples, and learning tracks.
