This chapter discusses ethical and legal aspects of biomedical research. After highlighting the evolution and acceleration of rule-making in this setting, it differentiates between research and experimentation, and articulates a core regulatory concept, namely risk. It then covers ethical codes and legal instruments in human biomedical research, research ethics committees, randomised controlled trials, and experimental treatment, paying particular attention to informed consent and research involving people lacking capacity. It also addresses the unethical researcher, compensation for personal injury in research, research involving human tissue and personal data, and new approaches to research governance.
20. Biomedical Human Research and Experimentation

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