**Table 3.** Definitions of Regulatory Challenges

| Regulatory Challenge | Definition | Reference |
|---|---|---|
| Common Rule | The "Common Rule" is the popular term for the Federal (U.S.) Policy for the Protection of Human Subjects 45 CFR part 46, which outlines the criteria and mechanisms for IRB review of human subjects research. | Office for Human Research Protections (2016)[1] |
| Community Consultation | The requirement for community consultation is one of the special protections provided whenever an Exception From Informed Consent is granted for emergency research. It serves as a "vehicle to listen to the community's interests and concerns, to address ethical issues, and to communicate information about the research to the community." | Ragin, et al. (2008)[2] |
| Enrollment | Determining eligible research participants for a research study. | Chamberlain, et al. (2009)[3] |
| Exception from Informed Consent (EFIC) | EFIC allows patients to be treated as part of research studies under special and rare circumstances. It can only be used in life-threatening emergencies, when there is a possibility for direct benefit to participants, and when consent is not possible. These studies are very public and transparent and have been discussed in the community. | Klein, et al. (2018)[4] |
| Human Subject Protection | Human Subjects Protections refers to the federal, state, and institutional policies, procedures, and ethical considerations that protect the rights and welfare of people who participate in research as the subjects of that research. | Perlman (2008)[5] University of Michigan (2022)[6] |
| Informed Consent | The process in which a health care provider/researcher educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. | Shah et al. (2021)[7] |

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|---|---|---|
| Institutional Review Board (IRB) | An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. This group has been formally designated to review and monitor biomedical research involving human subjects. | Mansbach, et al. (2007)[8] |
| Legally Authorized Representative (LAR) | A person authorized under applicable law to consent on behalf of a prospective human subject to the subject's participation in a research study and to authorize the use or disclosure of protected health information. | Gillenwater (2008)[9]<br>Biros, et al. (2015)[10] |
| Liability | Legal risks associated with research involving human subjects. | Kapp (2006)[11] |
| Participant Incentives | Something made to compensate individuals for participation in research studies. | Bernstein and Feldman (2015)[12] |
| Patient Perception | Refers to the patients' view of research. | Ventolini, et al. (2014)[13] |
| Patient Safety | Prioritizing patient/participant welfare. | Iserson (2007)[14] |
| Recruitment | Registering or entering eligible research participants into a research study. The dialogue that takes place between an investigator and a potential research participant. | Patel, et al. (2003)[15] |
| Research Ethics | Norms of conduct that distinguish between acceptable and unacceptable behavior in research. A set of ethical guidelines that guide us on how scientific research should be conducted and disseminated. | Shah (2011)[16] |
| Waiver of Informed Consent (WIC) | A waiver of informed consent requires a researcher to seek approval from an ethical review body to use a person's personal information or personal health information without actually obtaining consent directly from the individual in order to use that information in a research project. | Salzman, et al. (2007)[17]<br>Klein, et al. (2018)[4] |

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