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| The purpose of this worksheet is to provide support for investigators conducting an emergency use of a test article in a life threatening situation and Designated Reviewers reviewing an emergency use of a test article in a life threatening situation. This worksheet is to be used when overseeing emergency use of a test article in a life-threatening situation. It does not need to be completed or retained. | | |
| Emergency Use of a Drug or Biologic | | |
| 1. Exemption Criteria for Emergency Use of a Drug or Biologic (All of the following are “Yes”) | | |
| Yes  No | The patient is (was) confronted by a disease or condition that is (was) either:  Life-threatening meaning diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.  Severely debilitating meaning diseases or conditions that cause major irreversible morbidity. | |
| Yes  No | The situation necessitates (necessitated) the use of the investigational article: | |
| Yes  No | No standard acceptable treatment is (was) available. | |
| Yes  No | There is (was) NOT sufficient time to obtain IRB approval. | |
| Yes  No | The emergency use will be (was) reported to the IRB within 5 working days. | |
| Yes  No | Any subsequent use of the investigational product at the institution will have prospective IRB review and approval. | |
| Yes  No | The FDA has (had) issued an IND. | |
| Yes  No | The use is (was) **NOT** subject to DHHS regulation (See **WORKSHEET: Human Research Determination (HRP-309)**) | |
| **One of Sections 2, 3, or 4 must be met** | | |
| 1. Consent Criteria (All of the following are “Yes”) | | |
| Yes  No | Informed consent will be (was) sought from the patient or the patient’s legally authorized representative, in accordance with and to the extent required by 21 CFR §50. See WORKSHEET: Criteria for Approval and Other Considerations (HRP-311) | |
| Yes  No | Informed consent will be (was) documented, in accordance with and to the extent required by 21 CFR §50.27. See WORKSHEET: Criteria for Approval and Other Considerations (HRP-311) | |
| 1. Exception Criteria with Prospective Confirmation by an Independent Physician (All of the following are “Yes”) | | |
| Yes  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. | |
| Yes  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. | |
| Yes  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. | |
| Yes  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. | |
| Yes  No | Before the use of the test article a physician who is (was) not otherwise participating in the clinical investigation will certify (has certified) in writing that the above items are (were) true. | |
| 1. Exception Criteria with Retrospective Confirmation by an Independent Physician (All of the following are “Yes”) | | |
| Yes  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. | |
| Yes  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. | |
| Yes  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. | |
| Yes  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. | |
| Yes  No | Before the use of the test article a physician who is (was) not otherwise participating in the clinical investigation was unable to certify in writing that the above items are true. | |
| Yes  No | Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient. | |
| Yes  No | Time is (was) not sufficient to obtain the independent determination a physician who is (was) not otherwise participating in the clinical investigation. | |
| Yes  No | The investigator will submit (has submitted) the above written certification to the IRB within 5 working days after the use of the test article | |
| Yes  No | After the use of the test article a physician who is (was) not otherwise participating in the clinical investigation will certify (has certified) in writing within 5 working days after the use of the article that the above are true. | |
| Emergency Use of a Device | | |
| 1. Exemption Criteria for Emergency Use of a Device (All of the following are “Yes”) | | |
| Yes  No | The patient is (was) confronted by a disease or condition that is (was) either:  Life-threatening meaning diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.  Severely debilitating meaning diseases or conditions that cause major irreversible morbidity. | |
| Yes  No | No generally acceptable alternative for treating the patient is (was) available. | |
| Yes  No | Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use. | |
| Yes  No | The emergency use will be (was) reported to the IRB within 5 working days. | |
| Yes  No | Any subsequent use of the investigational product at the institution will have prospective IRB review and approval. | |
| Yes  No | The use is (was) **NOT** subject to DHHS regulation (See **WORKSHEET: Human Research Determination (HRP-309)**) | |
| Yes  No  N/A | | The treating physician will obtain (has obtained) an independent assessment by an uninvolved physician. (**“N/A”** if there is insufficient time to obtain an independent assessment) |
| Yes  No  N/A | | If an IDE exists, the physician has (had) authorization from the sponsor. (**“N/A”** if there is no IDE) |
| Yes  No  N/A | | If an IDE does not exists, the physician will notify (has notified) FDA of the emergency use. (**“N/A”** if there is an IDE) |
| **One of Sections 6, 7, or 8 must be met** | | |
| 1. Consent Criteria (All of the following are “Yes”) | | |
| Yes  No | Informed consent will be (was) sought from the patient or the patient’s legally authorized representative. | |
| Yes  No | Informed consent will be (was) documented. | |
| 1. Exception Criteria with Prospective Confirmation by an Independent Physician (All of the following are “Yes”) | | |
| Yes  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. | |
| Yes  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. | |
| Yes  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. | |
| Yes  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. | |
| Yes  No | Before the use of the test article an uninvolved physician will certify (has certified) in writing that the above items are (were) true. | |
| 1. Exception Criteria with Retrospective Confirmation by an Independent Physician (All of the following are “Yes”) | | |
| Yes  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. | |
| Yes  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. | |
| Yes  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. | |
| Yes  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. | |
| Yes  No | Before the use of the test article an uninvolved physician was unable to certify in writing that the above items are true. | |
| Yes  No | Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient. | |
| Yes  No | Time is (was) not sufficient to obtain the independent determination an uninvolved physician. | |
| Yes  No | The investigator will submit (has submitted) the above written certification to the IRB within 5 working days after the use of the test article | |
| Yes  No | After the use of the test article an uninvolved physician will certify (has certified) in writing within 5 working days after the use of the article that the above are true. | |