

**Recommendations for Implementation of Community Consultation and Public
Disclosure under the FDA “Exception from Informed Consent Requirements for
Emergency Research”**

**An American Heart Association Scientific Statement
from the Emergency Cardiovascular Care Committee**

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Summary

In addition to the usual requirement of appropriate study design and Institutional Review Board (IRB) approval, research studies done under the Food and Drug Administration (FDA) and Department of Health and Human Services regulations: “Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency Research” (21 CFR 50.24)¹ require Community Consultation and Public Disclosure. This Scientific Statement discusses the general issues related to consent in emergency circumstances and provides a template to help IRBs implement Community Consultation and Public Disclosure appropriately.

Introduction

Over 300,000 Americans die each year from catastrophic medical and surgical emergencies.^{2,3} New interventions, based on sound research, could save lives. These research studies must be done in an ethical framework that traditionally includes obtaining prospective informed consent from the research subject. The ethical framework for the conduct of Human Research began with the development of the Nuremberg Code^{4,5} in 1949. This code states that (1) informed consent of volunteers must be obtained without coercion of any form, (2) human experiments should be based on prior animal experiments, (3) the anticipated scientific results should justify the experiment, (4) only qualified scientists should conduct medical research, (5) physical and mental suffering should be avoided, and (6) no expectation of death or disabling injury should be expected from the research study.

The declaration of Helsinki⁶ was issued in 1964 and defines rules for clinical research. It repeats the ethical concerns stated in the Nuremberg Code, but also gives a provision for enrolling

certain patients in clinical research without their consent, by using either proxy consent, or waiver of consent in minimal risk studies.

The subsequent Belmont Report⁷, which was published in 1979, is the cornerstone of ethical principles upon which current federal regulations for the protection of subjects are based. The Report conveys the three major premises of ethical conduct of studies: respect for persons, beneficence, and justice. The Report also provides elements used by Institutional Review Boards for evaluating the ethical standards for individual research proposals. The ethical principles presented in both the Belmont Report and the Declaration of Helsinki have been expanded and clarified in the most recent guidelines published by the Council for International Organizations of Medical Sciences (CIOMS)⁸, especially for providing guidelines for applying ethical standards in local circumstances.

A dilemma arises in research studies of interventions for life-threatening emergencies, such as cardiac arrest, catastrophic neurological emergencies, and some instances of major trauma. In these circumstances, a victim may be eligible for a research study, but be unable to give prospective consent due to unconsciousness, or severe alteration in cognition, caused by the life-threatening emergency. Often with such research protocols, the subject must be enrolled immediately so that the potential physiological effects of the experimental intervention can be maximized before the onset of irreversible organ damage^{9,10}.

The FDA defines the “therapeutic window” as “the time period, based on available scientific evidence, during which administration of the test article might reasonably produce a demonstrable clinical effect.”¹¹ It is this therapeutic window that is limited or non-existent for research studies of life-threatening emergencies. There generally is not time to seek out a legally authorized patient representative for disclosure and consent. In addition, consent under such emergency circumstances may not meet the standards of informed consent, since there is little time for the investigator to explain the study, and little time for the patient representative to assess the various treatment options available.¹² In addition, the emotional state of the patient representative may eliminate the possibility

of reflecting objectively on the situation. Obtaining informed consent is especially difficult in pediatric populations where it has been shown that “the emotional trauma of the diagnosis decreases a mother’s ability to absorb and understand vital information, and the emergent nature of the children’s condition and the urgency to begin treatment further compromise informed consent.”¹³

Clinical trials involving research on emergency patients who were unable to give prospective informed consent were traditionally carried out in the United States by either receiving a waiver of informed consent from the local IRB, or by deferred consent.^{14,15} In 1993, however, the Office for Protection from Research Risks (OPRR) at the National Institutes of Health and the FDA questioned the legality of the deferred consent practice (45 CFR 46.102(i)).¹⁶ Because of problems with obtaining consent in studies of life threatening emergencies,^{17,18} and its impact on performing such studies, a Coalition Conference of Acute Resuscitation and Critical Care Researchers was held in October 1994. Representatives from over 20 organizations participated in discussions that explored informed consent in emergency research and produced consensus recommendations.¹⁹ In 1996, the FDA and the Department of Health and Human Services published regulations (21 CFR 50.24)¹ for the ethically and legally acceptable conduct of emergency research. Emergency research must operate under exemption from consent, either because of no or minimal risk, or through community exception of consent regulations as outlined by the Office for Human Research Protections (OHRP) and the FDA. These guidelines aim to protect patients from participation in a study they would not consent to if they had decisional capacity. For research that is subject to FDA regulation (i.e. conducted under an Investigational Device Exemption (IDE) or Investigational New Drug (IND) permit), exception from consent can be applied to emergency research if explicit criteria are met (table 1): a) an IDE or IND is in effect, b) the research involves human subjects who cannot consent because of their emerging life-threatening medical condition for which available treatments are unproven or unsatisfactory, c) the intervention must be administered before informed consent from the patient’s legally authorized representative is feasible, d) the sponsor has prior written permission from the FDA, e) an independent

data monitoring committee exists, and f) the relevant IRB has documented that these conditions were met. In addition, the ethical framework for performing such studies mandates that there is an independent assessment of the risks and benefits of the protocol.

For all research that is supported by federal funding (e.g.: NIH), even if the study does not use a drug or device regulated by the FDA, similar criteria are required to determine whether exception to informed consent is warranted for an emergency research study. In addition, for research that is not supported by federal funding or subject to FDA regulation (e.g. a trial of a novel method of manual cardiopulmonary resuscitation), IRBs generally apply similar criteria to determine whether exception from consent is warranted for an emergency research study.

Prior to the initiation of the study, **Community Consultation** and **Public Disclosure** must be provided for each emergency research protocol for which an exception from informed consent is requested.¹ In March 2000, the FDA issued “Draft Guidance” to help clarify the concepts of community consultation and public disclosure.¹¹ This report stated: “[C]ommunity consultation means providing the opportunity for discussions with, and soliciting opinions from the community(ies) in which the study will take place and from which study subjects will be drawn.” The three primary goals of the community consultation process are: (1) to explain the nature of the research, with its attendant risks and benefits, (2) to state that informed consent will not be obtained from individual subjects prior to study participation, and (3) to explain the process by which potential subjects can refuse to participate in research studies.¹¹ The FDA guidance defines public disclosure as “...dissemination of information about the emergency research sufficient to allow a reasonable assumption that communities are aware that the study will be conducted, and later, that the communities and scientific researchers are aware of the study results.”¹¹

The regulations indicate that each IRB is to exercise its own discretion in determining appropriate community consultation activities and public disclosure, allowing considerations specific to the local community(ies) to be taken into account. The regulations do not explicitly state the

amount or types of community consultation and public disclosure that need to be done to achieve compliance, although the FDA Guidance document does give some general considerations.¹¹ These requirements for community consultation and public disclosure, though reasonable, sometimes lead to delays in obtaining approval for research studies using the emergency exception process. Each IRB may lack experience in determining what types of consultation and disclosure are necessary. In addition, there is ambiguity in the regulations as to how individual IRBs should implement such community consultation and public disclosure. Shah and Sugarman examined emergency research protocols at 36 centers and reported that to satisfy the public disclosure requirement the majority of these centers used a one-way disclosure method (press releases, institutional and local newsletters, radio and television announcements). A minority of the centers reported using two-way disclosures with the community, including public forums, telephone polls and written communications.²⁰

Community Consultation and Public Disclosure Template

The purpose of this document is to provide guidance for implementation of community consultation and public disclosure. A template is presented which (1) provides for quantification of the minimum requirements that an IRB might adopt, (2) gives examples to help IRBs quickly become familiar with the process of implementing and reviewing studies proposed with Exception to Informed Consent, and (3) proposes that trials of interventions approved by the FDA for the indication being studied should require different levels of community consultation and public disclosure than studies of unapproved interventions. The template gives a common interpretation of the requirements, and provides a list of actions acceptable for the implementation of community consultation and public disclosure.

Ethics

The guiding ethical principle for the template is that there is a range of actions that are acceptable to protect subjects' autonomy, dependent on the risk of the study. The risk referred to here is the incremental risk of participation in the proposed study, over and above the risks of having sustained a life threatening emergency and being treated with standard interventions. The higher the risk of the study, the more stringent are the actions that are required to protect subjects' autonomy. Since there is a range of risk associated with different study interventions, different levels of community consultation and public disclosure can be used to balance appropriately subjects' autonomy with the public good.

A trial of an approved therapy should not require the same level of community notification and consultation as one where non-approved or not-generally-accepted interventions are being introduced for the first time. For interventions that were not approved by the FDA, the risk of the therapy could be incrementally higher, and the level of community consultation and public disclosure for the study should similarly be higher.

We therefore propose that it is ethically acceptable to stratify the intensity of community consultation and public disclosure based upon the anticipated incremental risks to subjects of participating in a research study. We acknowledge that any research study may have unanticipated risks, but we base our argument for stratifying community consultation and public disclosure on the reasonable and prudent prediction of subject risk.

Our proposal regarding stratifying community consultation is analogous to how IRBs currently review research protocols and informed consent documents. For example, IRB review of a protocol that studies unlinked serum samples will not require the same considerations as a project involving the use of a novel immunosuppressive agent in kidney transplantation. The study of unlinked serum samples may be considered to have minimal risk and therefore be eligible for expedited review, while the transplantation study requires standard IRB review. Similarly, the informed consent document

may be shorter and simpler for the serum sample study than for the transplantation study. Indeed, for the transplantation study, the IRB may suggest in addition to an extensive consent protocol, the use of supplemental educational material or the involvement of a patient advocate to ensure that subjects fully understand the risks, benefits and alternatives to participation. Our point is that while all emergency research that is not minimal risk requires some level of public disclosure and community consultation, emergency research studies that have less incremental risk, and are not politically and culturally controversial, may be performed ethically with lesser degrees of community consultation and public disclosure than would be needed for high risk or controversial studies.

Stratification of Risk

This template breaks studies into categories of minimal, low, intermediate, and high incremental risk. Any sudden, catastrophic, life threatening condition places patients at high risk for substantial morbidity and mortality. Instead of paying heed only to the inherent risk of the underlying disease, which is present whether the patient is enrolled in the study or not, we recommend evaluating the incremental risk from participating in the proposed study. That evaluation can then be used to determine the degree of community consultation and public disclosure appropriate for the proposed study.

Certain studies are justifiable without documented consent under minimal risk criteria. Consider the study of a therapy approved by the FDA for the indications being studied being compared to another therapy that was approved or did not need approval (e.g.: manual CPR). The study likely would carry a risk that was minimally above the risk of being treated with either approved therapy. In the absence of a research protocol, physicians could ethically and legally choose to treat patients with a life-threatening condition with either of these interventions. The only additional factors introduced by a research study of these interventions are 1) that the patients are being randomized to one of the approved interventions, and 2) the loss of privacy and confidentiality during review of the clinical

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record after the intervention has been applied. Therefore, if the randomization procedure does not introduce any significant delay in applying the approved therapies, such a study is justifiable without documented consent under minimal risk criteria. The rationale for not having an informed consent document is described in the preamble to the final rule for 21 CFR 50:

“The agency thinks that it may not always be possible to develop a meaningful informed consent document for continued participation in the research, because the relevant information may vary significantly depending upon when it becomes feasible to provide the information to the subject or legally authorized representative. The agency is, therefore, not requiring that such a form be developed. The agency notes however that Sec. 50.24 (a)(6) places the responsibility on the IRB to review and approve ‘informed consent procedures and an informed consent document’ for use with subjects or their legal representatives, and procedures and information to be used in consultations with family members, in situations where use of such procedures is feasible.”²¹

During the comment period for these regulations, the agency received feedback that the subject should be able to choose to continue to participate fully in a study, to continue the intervention but not have their data included in the research database or results, or to discontinue the intervention and use of the subject’s data. This was rejected on the following grounds:

‘FDA regulations... require investigators to prepare and maintain adequate case histories recording all observations and other data pertinent to the investigation on each individual treated with the drug or exposed to the device. The agency needs all such data in order to be able to determine the safety and effectiveness of the device. The fact of having been in an investigation cannot be taken back. Also, if a subject were able to control the use (inclusion and exclusion) of his or her data, and particularly if the clinical investigation were not blinded, the bias potential would be immense.’²¹

The factors that can help decide the degree of incremental risk added by a particular study are shown in Table 2. We propose that IRBs use the following criteria to determine incremental risk:

(1) FDA labeling status of the investigational therapeutic drug or device, for studies of interventions; (2) an evaluation of whether the study introduces any additional risk of harm over that of simply using the investigational therapeutic drug or device (such as any delays in applying therapy that may be introduced by the randomization process); (3) the degree of invasiveness and need for real-time clinical decisions, for studies of diagnostics; and (4) the potential sensitive nature of the study from the community(ies)' perspective, including political cultural and religious considerations. For a therapeutic intervention, therefore, the study would have minimal, low, intermediate, or high incremental risk based on the FDA labeling status of the therapy and the assessment of whether there was minimal risk of being in the study (Table 2, "Intervention" row), unless it were placed in a higher risk category based on the community(ies)' sensitivity (Table 2, bottom row). The same would be true for the study of a diagnostic, where the type of diagnostic would place it in minimal, intermediate or high risk categories based on the degree of invasiveness, the need for real-time decision making, and whether the diagnostic is FDA approved (Table 2, "Diagnostic" row), unless it were placed in a higher risk category by the perceived community(ies)' sensitivity (Table 2, bottom row).

Levels of Community Consultation and Public Disclosure

Once the degree of incremental risk is determined, we propose that the amount and types of community consultation and public disclosure be guided by Table 3. For minimal risk studies, no community consultation or public disclosure is required, although minimal community consultation should be considered. For low incremental risk studies, minimal community consultation would be needed. For example, review and feedback from an appropriate group, committee, panel or organization representative of the study community could allow appropriate community consultation without excessive time being needed to wait for public comment from a published advertisement. Alternatively, there could be solicitation through a website or public notices (such as through the mass

media), with a call-in number and/or web address provided for feedback. For a high incremental risk study, however, more community consultation would be required, including an appropriate number of mass media solicitations, community meetings, and contact with prominent community organizations. Specific examples of community consultations and public disclosures are available at:

www.americanheart.org/emergencyexception. We emphasize that the recommendations of Table 3 are simply guidelines. Individual IRBs will set their own standards based on their individual considerations. We also emphasize that involvement of the community should include attempts to consult with targeted, at-risk, or interested, populations.

Definition of Community for Pediatric Studies

There is a unique problem in the definition of what constitutes a “Community” for pediatric studies. For many pediatric populations, the “Community” could be defined to include a group of patients with a specific disease, their families, as well as the appropriate health care providers (especially in the in-hospital environment). In these types of situations, rather than a particular geographic based community, consultation with the “Community at risk” may be most appropriate. This process should be differentiated, however, from prospective informed consent of all patients at risk, as the latter process may not be feasible due to the potentially large numbers of patients involved.

Definition of Community for Hospital-Based Studies

Also there is a unique problem in the definition of what constitutes a “community” for hospital-based studies. For many hospital populations, the “community” could be defined to include a group of patients who present to the ambulatory, emergency and wards of the hospital, their families, visitors, as well as the appropriate health care providers. In these types of situations, where it is not feasible to consent every individual who enters the grounds of the hospital, consultation with the “community at risk” may be most appropriate. This process should be differentiated, however, from prospective

informed consent of all patients at risk, as the latter process may not be feasible due to the potentially large numbers of patients involved.

DISCUSSION

We propose that it is ethically acceptable to stratify the intensity of community consultation and public disclosure based upon the anticipated incremental risks to subjects of participating in a research study. We propose, therefore, a template that breaks studies into categories of minimal, low, intermediate, and high incremental risk. Low incremental risk studies should require only minimal community consultation and public disclosure, while high incremental risk studies would require more extensive community consultation and public disclosure. This template should help IRBs in deciding what types and how much community consultation and public disclosure are needed for studies of emergency research done under the exception to informed consent process.

Standardization of community consultation and public disclosure are necessary because there has been uncertainty and hesitation by investigators and IRBs in interpretation of current procedures for implementing research with the exception of informed consent process.²² There are significant variations in local IRB's interpretation of what is necessary for fulfilling the FDA requirements for community consultation as well as what constitutes the proper venue for the community to provide feedback. These variations make it difficult for the investigator to judge what will be necessary for IRB approval at any particular institution and this often significantly prolongs the approval process, particularly for multicenter studies. IRB membership and experience changes over time so that the investigator is faced with an evolving set of criteria that needs to be met for initial, as well as, continuing approval.

In one large multi-center trial of 24 sites studying public access defibrillation using FDA approved devices within the approved labeling, it took up to 404 days (median 108), and up to 7 submissions (median 2), to obtain IRB approval using the emergency exception process.²² The types

and numbers of activities undertaken at each site to fulfill the community consultation and public disclosure requirements were quite diverse. There were public meetings, press releases, letters, brochures, newsletters, emails, radio, television or print advertisements, notices, feature stories, and radio and television appearances. Of over 1000 comments received, 96% were reported as “positive,” and only 1% were reported as negative”.²² No IRB rejected the project for approval based on the negative comments, and the study protocol was not changed in any location based on the comments received.

IRB approval can be even more difficult if the drug or device to be studied has not been approved for sale by the FDA. The issue for the IRB is that they are asked to approve a research study where a drug or device which has not been approved by the FDA is used on a test subject without their consent, there is likely to be a fatal outcome because of the inherent disease state, and the next of kin will be notified of these details. In many emergency situations, such as cardiac arrest, mortality may exceed 90%. This is precisely why the research is critical. Because of the large numbers of victims of these conditions, even small increases in survival could save many lives. Even if the experimental drug or device would reduce mortality from 90% to only 80% - that would translate into a potential saving of more than twenty thousand lives per year for that one therapy (i.e.: 10% of the > 200,000 cardiac arrest deaths per year). Some IRB’s have expressed great reluctance to approve such studies because of fear of liability,²³ and at least one IRB will not approve any studies using the exception to informed consent process.²⁴

Conclusion

In conclusion, obtaining informed consent from patients or surrogates is difficult in the setting of serious emergency conditions. Current regulations do allow studies to be performed with Exception to Informed Consent, but ambiguities in implementing studies under current regulations can be onerous for IRBs and investigators, and may discourage research to evaluate promising interventions

for Americans. We propose a template to help guide IRBs to comply with the Federal Regulations with appropriate balance between protecting eligible patients, and preserving the public good.

Table 1—Summary of the Exception from Informed Consent Requirements for Emergency Research (21CFR50.24)

Justifications

- 1) The research involves a medical condition or situation in which:
 - a) Human subjects are in a life-threatening situation.
 - b) Available treatments are unproven or unsatisfactory.
 - c) Evidence is necessary to determine the safety and effectiveness of particular interventions.
- 2) Obtaining informed consent is not feasible because:
 - a) The subject is not able to give consent due to his or her medical condition;
 - b) The intervention must be administered before obtaining consent from legal representative is feasible.
 - c) There is no reasonable way to identify eligible subjects prospectively.
- 3) Participation holds out the prospect of direct benefit to the subjects because:
 - a) Subjects face a life-threatening situation which requires intervention.
 - b) Preliminary investigations, including animal studies, and related evidence suggest that this intervention may provide a direct benefit to the individual subject.
 - c) The risks are reasonable.
- 4) The clinical investigation could not practicably be carried out without the waiver.

Obligations of the Investigator

- 5) The proposed study protocol defines the length of the potential therapeutic window, and the investigator:
 - a) Commits to attempt to contact and, if feasible, to obtain consent from a legally authorized representative for each subject within that window of time; and
 - b) If a legal representative is not available, commits to attempt to contact within that window some other family member and ask if that family member objects to the subject's inclusion; and
 - c) Will summarize the efforts made to contact legal representatives and family members and make this information available to the IRB at the time of continuing review.
- 6) Consultation with representatives of the communities in which the research will be conducted.
- 7) Public disclosure to the communities where the research is conducted:
 - a) Prior to initiation of the trial regarding the study plans, risks and benefits;
 - b) After completion, of the results and subject demographics.
- 8) Perform the study under a separate investigational new drug application (IND) or investigational device exemption (IDE) from the Food and Drug Administration, even if an IND or IDE already exists.

Obligations of the IRB

- 9) The IRB has reviewed and approved procedures and documents for:
 - a) Use in situations when obtaining informed consent is feasible;
 - b) Use when providing an opportunity for a family member to object is feasible.
- 10) The IRB is responsible for assuring that procedures are in place to:
 - a) Inform each subject, or a legally authorized representative or family member (if the subject is incapacitated) of his or her inclusion in the study and details of the study;
 - b) Inform each subject or representative that he or she may discontinue participation in the trial;
 - c) Inform subjects who become competent after initial notification to representatives of incompetent subjects;
 - d) Inform a legally authorized representative or family member of subjects who die prior to notification about the trial.
- 11) If an IRB determines that it cannot approve a proposed study because it does not meet the criteria for justifying the need for a waiver or for other ethical concerns, the IRB must provide these findings promptly to the investigator and sponsor in writing.
- 12) The IRB must retain the determinations and documentation required by the above regulations for three years after completion of the investigation.

Obligation of the Sponsor

- 13) Develop the protocol in collaboration with appropriate investigators.
- 14) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation.
- 15) If an IRB denies approval of a protocol per item 12, the sponsor of the investigation must promptly disclose this information to the FDA, the clinical investigators and other IRBs that have been or are asked to review the same or a substantially equivalent trial. The sponsor must track all information disclosed and assure that disclosed information is placed on the FDA's public docket.

Table 2. Assessment of Incremental Risk of Research Studies.

Study Type	Potential incremental risk added by study			
	Minimal	Low	Intermediate	High
Intervention (Device/ drug)	1) FDA approved for proposed study indication 2) and/or already in clinical use for study indication 3) and have minimal risk of harm from being in the study. (e.g.: Approved mechanical CPR device vs standard CPR; amiodarone vs lidocaine)	1) FDA approved for proposed study indication 2) and/or already in clinical use for study indication 3) and have higher than minimal risk of harm from being in the study	1) FDA approved for clinical use, 2) but not for the study indication.	Not FDA approved for any indication yet.
Diagnostic (Test/device/feature)	1) Non-invasive, 2) and not used for real-time clinical decisions. (e.g.: non-invasive monitor, low volume blood drawing)		1) Minimally invasive, 2) and not used for real-time clinical decisions. (e.g.: transconjunctival oxygen saturation)	1) More than minimally invasive, 2) or used for real-time clinical decisions, 3) or not FDA approved. (e.g.: intracranial pressure monitor),
Community's potential sensitivity (Political, cultural, religious)	Very unlikely to have community sensitivity	Very unlikely to have community sensitivity	Possibly to have community sensitivity	Likely to have community sensitivity

For a therapy, the study would have minimal, low, intermediate, or high incremental risk based on the FDA labeling status of the therapy, and the assessment of whether there was minimal risk from being in the study (“Intervention” row), unless it were placed in a higher risk category based on the community(ies)’ sensitivity (bottom row). For a diagnostic: the study would have minimal, intermediate or high risk categories based on the degree of invasiveness and the need for real-time decision making (“Diagnostic” row), unless it were placed in a higher risk category by the perceived community(ies)’ sensitivity (bottom row).

Table 3: Levels of Community Consultation and Public Disclosure suggested at different degrees of incremental risk.

	Potential incremental risk added by study		
	Low	Intermediate	High
Community Consultation Options	Review and feedback from an appropriate group, committee, panel or organization representative of the study community. Alternatively, consider solicitation through website or public notices (such as through a mass media piece), with a call-in number and/or web address provided for feedback	1) As in Low, 2) Plus consider solicitation through website or public notices (such as through a few mass media pieces). 3) Call-in number and/or web address provided for feedback	1) Review and feedback from at least one group, committee, panel or organization representative of the study community, 2) Public forum(s) or presentation at municipal government meeting(s) in the study community. 3) Solicitation via a number of mass media pieces. 4) Call-in number and/or web address provided for feedback
Public Disclosure Options	Single targeted effort deemed most likely to reach study community: This could be through a mass media piece or distribution of information in more focused manner to likely subjects. (e.g.: targeted: poster, brochure or newsletter article in senior citizen center where study will be conducted.)	At least one targeted effort and a mass media piece. Consider website.	Multiple efforts, including both targeted efforts and mass media pieces, as deemed necessary to reach the community adequately. Website recommended.
Patient / family notification of participation	Reasonable attempts required for written communication regardless of patient survival status (e.g.: letter, including invitation to meet with investigator or study coordinator to discuss)		

For minimal risk, no community consultation or public disclosure is needed, although a single announcement could be considered. A mass media piece refers to a newspaper article or advertisement, or a radio announcement, or a television spot.

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