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Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials

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Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff

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For questions about this document, contact the Office of Clinical Evidence and Analysis, DCEA1: Division of Clinical Science and Quality at CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

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Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials

Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this document is to provide Institutional Review Boards (IRBs), industry, clinical investigators, and Food and Drug Administration (FDA) staff factors to consider when evaluating the appropriateness of a live case presentation within a clinical investigation[1] conducted under an investigational device exemption (IDE) application.[2] This document provides guidance on important information about a live case presentation that should be provided as part of an original IDE application or a supplement to an IDE application when requesting inclusion of a live case presentation during a clinical investigation. Applications and supplements that include a live case presentation are referred to generally as "requests" throughout this document.

A live case presentation is a live or pre-recorded broadcast of a surgical or percutaneous procedure, typically narrated by the operator (or a discussant other than the operator), with or without expert panel and/or audience interaction. These presentations are typically broadcast at scientific meetings to increase awareness of the clinical investigation and recruit

[1] For purposes of this guidance, the terms "clinical investigation," "investigation," "study," and "research" are used synonymously.

[2] Although this guidance is written primarily for device investigations that require submission of an IDE application to FDA (e.g., significant risk devices), the information may also be applied to non-significant risk (NSR) device studies.

prospective investigators and study subjects. Video recordings or broadcasts that are outside the scope of this guidance include devices or procedures that automatically capture video during use (e.g., laparoscopic and thorascopic devices), telemedicine, and recordings that are routinely captured and broadcast as part of an institution's standard policies. Investigators should follow the institution's policies regarding the ability to share these kinds of video recordings in a manner consistent with applicable laws and regulations.[3]

Our expectation is that very few investigations under an IDE will include live case presentations. However, by increasing awareness of the study for health care professionals and eligible subjects, live case presentations may lead to new therapies being made available sooner. Because live case presentations are often intended to recruit investigators and subjects, it is generally not appropriate to request a live case presentation for a clinical investigation nearing completion, though exceptions may exist.

Not all clinical investigations are appropriate for live case presentations. For example, certain high-risk procedures that may adversely impact the subject, or certain investigations involving children, may not be suitable for live case presentations. When reviewing an IDE application, FDA intends to evaluate whether the requested live case presentation raises the risk profile of participation for subjects, such that conducting the live case presentation is not justified. A live case presentation may not be appropriate for novel devices for which the risk profile is unknown or only limited information is available. On the other hand, an acceptable live case presentation could include a high-risk procedure in which the risks are well-understood, risk mitigations are in place (e.g., the case is being performed by a team of operators with high levels of expertise at a site with an excellent record of both performing the procedure and performing live case presentations), subjects are selected with appropriate clinical and anatomic characteristics (e.g., a subject that does not have complex anatomy or is not at the highest risk for injury should a complication occur), and the informed consent process is conducted in accordance with 21 CFR part 50.

Investigations involving a significant risk device,[4] including those investigations involving live case presentations, require prior approval by FDA and an IRB (21 CFR 812.20(a)(2) and 21 CFR 812.62). Investigations involving a non-significant risk device, including those investigations involving live case presentations, must be approved by an IRB, but non-significant risk device investigations generally do not require the submission of an IDE application to FDA (21 CFR 812.2(b)(1)(ii)).

[3] Additional federal statutes or regulations, administered by FDA or other federal agencies, not mentioned herein are outside of the scope of this guidance, but may apply to clinical investigations, including live case presentations.

[4] A significant risk device is defined as an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject (21 CFR 812.3(m)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

This guidance is intended, in part, to improve the quality of information about live case presentations submitted by sponsors as part of an investigational plan in an original IDE application or supplement to an IDE application and to ensure consistency in the review of requests to include live case presentations. It describes measures we recommend sponsors take to ensure adequate human subject protection, follow-up, reporting, and data analysis for live case presentations. Because there are unique safety considerations, and possible differences between outcomes of subjects participating in live case presentations compared to subjects not participating in live case presentations, this guidance was developed for IRBs, industry, clinical investigators, and FDA review staff to support best practices.

III. Human Subject Protection Measures

FDA and IRBs consider the adequacy of human subject protection measures when reviewing an investigation involving a live case presentation. Investigations involving live case presentations conducted under 21 CFR part 812, which may include investigations involving significant risk and non-significant risk devices, must be reviewed and approved by an IRB before they begin (21 CFR 812.62). The general standards for the composition, operation, and responsibility of IRBs that review FDA-regulated clinical investigations are outlined in 21 CFR part 56. The criteria for IRB approval of research, including research involving live case presentations of investigational devices, are outlined in 21 CFR 56.111. Among the approval criteria that may present particularly important questions for the IRB when evaluating an investigation involving live case presentations are the following:

1. Risks to human subjects are minimized in accordance with 21 CFR 56.111(a)(1);
2. Informed consent will be sought in accordance with and to the extent required by 21 CFR part 50 (21 CFR 56.111(a)(4));
3. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (21 CFR 56.111(a)(7)); and
4. When some or all of the subjects are children, the research complies with 21 CFR part 50, subpart D (21 CFR 56.111(c)).

A. Risk Analysis

IDE applications submitted to FDA must include an investigational plan with a risk analysis under 21 CFR 812.20(b)(2) and 21 CFR 812.25(c). A modified risk analysis is likely needed when an investigational plan is revised to include a live case presentation and submitted as a supplement to the original IDE application. Reasonable efforts should be undertaken to identify and discuss in detail all probable risks and benefits of conducting the procedure as a live case presentation. The risk analysis should describe and analyze all increased risks to which the subject will be exposed by participating in a live case presentation, discuss the

manner in which these risks will be minimized, and provide a justification for the live case presentation consistent with 21 CFR 812.25(c).

Live case presentations may increase risks to subjects in several ways.[5] The potential additional risks that should be addressed in the original or modified investigational plan may include, but are not limited to, the following:

- Increased risk of infection due to the increased number of non-medical personnel and broadcast equipment in the sterile environment of the operating room or procedure room;
- Prolongation of the medical procedure, resulting in increased blood loss, anesthesia time, radiation exposure, and risk of infection;
- Distraction of the operator and other medical personnel from the highly technical and/or high-risk procedure, which could negatively impact the procedure results;
- Increased pressure on the operator as a result of public scrutiny of the procedure, or conflicting advice from a panel of experts moderating the live case session, which could negatively impact the procedure results;
- Invasion of the subject's privacy in the operating room or procedure room because of the presence of persons not directly involved in medical care, as well as the public viewing of the subject's medical procedure; and
- Inadvertent broadcasting of the subject, subject identifiers, the subject's voice, or conversations in which the subject's identity is revealed.

A subject who agrees to participate in a live case presentation should have the same anticipated benefit as if that subject was participating in the clinical investigation and did not participate in the live case demonstration.

During a live case presentation that is being recorded and/or broadcasted in real time, a discussant/narrator, other than the operating surgeon, should participate to explain the procedure and answer questions. This recommendation is intended to reduce the risk of prolonging the procedure or distracting the surgeon performing the procedure. If the sponsor does not elect to use a discussant/narrator, this should be specified when the request for a live case presentation is submitted to the FDA in the original IDE application or supplement to an IDE application; this information should also be included in the submission to the reviewing IRB. In addition, FDA would expect to see the sponsor's rationale for not having a discussant/narrator other than the operating surgeon and any procedures that would be employed to help mitigate the potential risk of not using a separate discussant/narrator. FDA recommends recording the procedure to minimize the number of live case presentations conducted during the clinical investigation.

B. Informed Consent

A subject may be asked to participate in a live case presentation after enrolling in a study. It must be made clear to the subject that participation in a live case presentation is optional (see

[5] Sade RM, for the American Association for Thoracic Surgery Ethics Committee and The Society of Thoracic Surgeons Standards and Ethics Committee. *Broadcast of Surgical Procedures as a Teaching Instrument in Cardiothoracic Surgery*, J Thorac Cardiovasc Surg 2008; 136:273-7.

21 CFR 50.25(a)(8)). FDA recommends that the informed consent incorporate a statement that there is no additional direct benefit beyond the benefits of the clinical investigation, if any, conferred on the subject by his or her participation in the live case presentation. It should also be made clear to the subject that there will be no favoritism from the investigator as an acknowledgement or reward for consenting to participate in a live case presentation. The informed consent document and process must comply with the requirements of 21 CFR 50.20 and minimize the possibility of coercion or undue influence for subjects who are asked to participate in a live case presentation. Subjects should be able to enroll and continue their participation in the investigation without agreeing to participate in a live case presentation.

Legally effective informed consent for a subject's participation in a live case presentation must be obtained in accordance with 21 CFR part 50. The informed consent for a live case presentation may be a separate document, in which case, it should clearly outline any differences between the live case procedure and the study protocol. This separate document must include a description of any reasonably foreseeable risks, including any risks specifically associated with the live case presentation and any confidentiality/privacy risks pursuant to 21 CFR 50.25(a). A subject who participates in a live case presentation must be informed (typically in writing) by the investigator (or a person designated by the investigator) of these risks and of the investigational nature of the device pursuant to 21 CFR 50.27 and 21 CFR 50.25. The informed consent for a live case presentation should describe, where applicable:

1. Whether the procedure will be recorded for future viewing and/or broadcast to an audience during the conduct of the procedure;
2. That there is no additional direct benefit to the subject for participating in the live case presentation beyond the benefits of the clinical investigation, if any;
3. That it is not known whether participating in a live case presentation will affect clinical outcome compared to subjects who do not participate;
4. Any additional or increased risks posed by performing the procedure as a live case presentation, such as risks posed by increased anesthesia and/or procedure time, compared to the procedure not being performed as a live case presentation (see previous discussion under "Risk Analysis");
5. Any additional or increased risks related to subject confidentiality that may occur as a result of participation in the live case presentation, such as privacy concerns related to the live case presentation broadcast, and subsequent distribution and/or use of a video or other type of stored media of the procedure; and
6. Whether additional follow-up and evaluation may be warranted as a result of the subject's participation in a live case presentation and how such follow-up and evaluation may be different compared to the procedure not being performed as a live case presentation.

For significant risk studies, informed consent documents must be included in the original IDE application or supplement to an IDE application (21 CFR 812.20(b)(11)). The informed consent document(s) must be approved by the FDA and the IRB prior to beginning such a study or beginning the live case presentation (21 CFR 812.42). For nonsignificant risk

studies, the informed consent document must be approved by the IRB (21 CFR 56.109(a); 21 CFR 812.2(b)(1)(ii)).

C. Additional Considerations for Children

The Agency believes there will only be rare instances in which it might be appropriate to have live case presentations of children.[6] Live case presentations involving children should be reviewed by the IRB with particular concern for additional risks to the safety of the children during the procedure. In addition to the risks described in Section III.A, these live case presentations pose unique considerations. For example, children are smaller than adults on average, which may make the procedure involved more technically challenging. Safe performance of the procedure may therefore require a heightened degree of concentration, which may be more difficult to achieve given the distractions that may be associated with live case presentations.

In addition to other responsibilities assigned to IRBs under 21 CFR parts 50 and 56, each IRB must review clinical investigations involving children as subjects covered by 21 CFR part 50, subpart D and approve only those clinical investigations that satisfy the criteria described in 21 CFR 50.51, 50.52, or 50.53, and the conditions of all other applicable sections of 21 CFR part 50, subpart D (21 CFR 50.50 and 21 CFR 56.111(c)). The added risk of a live case presentation should present no more than minimal risk to the child. In addition, the IRB must determine that adequate provisions are made for soliciting the assent of the child when, in the judgment of the IRB, the child is capable of providing assent and that the permission of their parents or guardians is granted as set forth in 21 CFR 50.55.

IV. Information to Include in IDE Applications When Seeking to Conduct Live Case Presentations

FDA believes live case presentations performed during an investigation may affect the rights, safety or welfare of subjects enrolled in the clinical trial. Therefore, for investigations of significant risk devices conducted under an approved IDE, the sponsor of the investigation must obtain FDA approval of changes to the investigational plan per 21 CFR 812.35(a) and IRB approval per 21 CFR 812.62 prior to conducting a live case presentation (21 CFR 812.42). For investigations of non-significant risk devices, sponsors must obtain IRB approval per 21 CFR 812.2(b)(1)(ii) prior to changing the investigation to include a live case presentation.

Live case presentations have not generally been prospectively identified and described as components of the overall study design in original IDE applications. Requests for live case presentations have been submitted to the FDA as various supplements to an approved IDE application such as prospective requests for protocol deviations, changes to the investigational plan, or study expansion requests in accordance with 21 CFR 812.35(a). We recommend that the IDE supplement adding a live case presentation to the investigation be identified as a request for a live case demonstration.

[6] For the purposes of this guidance, FDA has adopted the term "children" as defined in 21 CFR 50.3(o).

Sponsors should consider whether they intend to conduct live case presentations early in development and include relevant information in the investigational plan section of the original IDE, where possible (see 21 CFR 812.25). The inclusion of live cases in a study may affect the overall study design, including the scientific soundness of the study and the way the data are analyzed. For example, subjects may be pre-selected to participate in the broadcast, which may result in breaking treatment assignment protocols, unblinding investigators and subjects, and introducing selection bias. Even if the study is designed as a single arm study, the live case presentation may represent a change to the approved research since there may be additional anesthesia time or other additional risks. Subjects may experience changes in treatment regimen or have their privacy compromised. Data analysis, risk analysis, and reporting may also be altered. Therefore, if live case presentations are anticipated for any part of an investigation at the time an original IDE application is submitted, the plan for the live case presentation should be discussed in the original IDE application.

The following information should be included when requesting approval for a live case presentation either when the original IDE application is submitted, or as a supplement to an IDE application:

- The total number of live case presentations anticipated over the duration of the study;
- A justification for the live case presentation; if more than one live case presentation is requested, provide a justification as to why more than one is necessary;
- The name(s), date(s), and location(s) of the event (if known) where the live case presentation will be broadcast and the investigational site where the procedure will be conducted;
- The name and qualifications of the operator/investigator performing the procedure, or reference to where the information is located if previously submitted or summarized in a different section of the IDE;
- A copy of the informed consent document(s) for the live case presentation to be used at each investigational site;
- A discussion of methods utilized to minimize risks; and
- A discussion of how the live nature of the case will affect the scientific soundness of the study and how the live case data will be addressed in the statistical analysis or otherwise be used to support device approval or clearance.

If it is not anticipated at the time of the original IDE, the live case presentation request should be submitted as a supplement to the original IDE in accordance with 21 CFR 812.35(a) at least 30 days prior to the planned presentation. This is because original IDE applications and supplements have a 30-day review period. The supplement may reference any information that was already included and approved in the original IDE.

If a live case presentation is anticipated at the time of the original IDE application, but specifics about the live case presentation are not known at that time, FDA intends to focus its review on the risk analysis, the informed consent, and the impact of live case presentations on the study design and data analysis.

FDA also has concerns related to clinical study execution as identified below. FDA therefore recommends that the following additional items be specifically addressed when designing or revising an investigational plan to include live case presentations:

- Live case presentations typically include prior subject selection and may result in unblinding the investigator and subject. The potential for investigator and selection bias should be addressed, as well as how this bias will be minimized;
- Sponsors should include a discussion of how subjects participating in live case presentations will be addressed in the planned endpoint analyses. For example, sponsors should specify if these subjects will be excluded from the overall effectiveness analysis and reported as a separate cohort. Sponsors should adjust sample sizes after considering whether subjects should be excluded from primary outcomes analyses;
- Since a live case presentation presumably means that a subject is receiving the investigational treatment, the IDE protocol for treatment assignment may be violated if there is a randomization schedule. The sponsor should address any impact of the live case presentation on the protocol's randomization schedule and how those changes, if any, could impact the study analysis;
- Live case presentations should not cause any significant changes to the investigational protocol, other than potentially altering treatment assignment if the trial is randomized. The sponsor should describe in detail and justify any anticipated changes to the protocol, including subject follow-up and evaluation;
- Data for subjects participating in live case presentations should be collected in accordance with the approved investigational plan and reported to FDA. FDA intends to review the data from the live case presentation for safety and effectiveness, whether the data are used in the statistical analysis or otherwise used to support a marketing submission. Live case presentations should be separately reported and also compared to the remaining investigational cohort in progress and final study reports as well as in any marketing submission;
- If an unanticipated adverse device effect (UADE) requiring investigation and reporting to the Agency and all reviewing IRBs (21 CFR 812.150) occurs during a live case presentation, it should be noted in the UADE report that it took place during a live case presentation with a discussion of how the nature of the live case presentation may have impacted the adverse event; and
- A risk analysis that includes a discussion of the potential increased risks to the subject posed by the live case presentation (21 CFR 812.25(c)).

The live case presentation should be conducted only at an investigational site by an investigator who has signed an agreement with the sponsor pursuant to 21 CFR 812.43(c) and is currently participating in the study under an approved IDE. Sponsors must not use live case presentations to promote or test market an investigational device or to represent that the investigational device is safe or effective for the purposes for which it is being investigated (21 CFR 812.7(a) and (d)).

As described above, live case presentations are often intended to recruit investigators and subjects to increase the likelihood of completing the investigation and are not integral to

completion of the surgical or percutaneous procedure that is being broadcast or recorded. The Agency believes that the potential increased risks associated with live case presentations are not appropriate for use of an investigational device (i.e., one that has not been approved or cleared by FDA) under Expanded Access.[7] In many cases, patients treated with an investigational device under Expanded Access would not meet the enrollment criteria for inclusion in a clinical investigation under an IDE or are otherwise unable to enroll in a clinical investigation (e.g., the clinical investigation has concluded or has reached enrollment capacity). The investigational device may present different or additional risks for these patients than for subjects enrolled in a clinical investigation under an IDE.

V. Data Collection and Reporting

The record-keeping requirements for investigators conducting an investigation that requires submission of an IDE application to FDA consists in part of maintaining records that include all relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated) (21 CFR 812.140(a)(3)(ii)). There should be no less data collection for live case presentations than there is for the general investigational cohort.

If an unanticipated adverse device effect occurs during a live case presentation, the investigator must report it to the sponsor and reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect (21 CFR 812.150(a)(1)). The sponsor must immediately conduct an evaluation of the unanticipated adverse device effect (21 CFR 812.46(b)(1)) and report the results of the evaluation to FDA and all reviewing IRBs and participating investigators within 10 working days after the sponsor first receives notice of the effect (21 CFR 812.150(b)(1)).

As mentioned above, live case presentations should not cause any significant changes to the investigational protocol. Generally, all per protocol follow-up appointments should be applicable to live case presentations. Information about the live case presentation should be provided in a progress report for the IDE at least annually, or as required by the approval requirements. The progress report required under 21 CFR 812.150(b)(5) should include the following information about the live case presentation:

- Summary information:
  - Diagnostic indications for the procedure;
  - Description of all differences between the live case procedure and the investigational protocol;
  - Name(s) of the investigator(s) involved in the live case presentation and their role(s) in the case (e.g., surgeon, narrator, etc.);
  - Investigational site;
  - The IRB(s) and IRB chair(s) that approved the live case presentation;
  - The name of the event at which the live case presentation was broadcast, date of the live case presentation(s), and the date(s) of the broadcast (if different from the date of the live case presentation); and
  - Location of the event for live case presentation(s).

[7] For more information about Expanded Access for investigational devices, see https://www.fda.gov/medical-devices/device-advice-investigational-device-exemption-ide/expanded-access-medical-devices.

- Subject-specific information:
  - The subject's identification codes for the particular study;
  - Subject demographics;
  - How the subject was selected, (e.g., fewest risk factors, prognosis);
  - Results and conclusions of the procedure, including a complete description of any adverse effects; and
  - Any other pertinent information relating to the safety of the device as used under conditions of the live case presentation (e.g., lot number, serial number, etc.).

This information should be provided for any live case presentation that was attempted, even if it was aborted for any reason. In addition, if a specific live case presentation was approved but not performed, this should be submitted to FDA in the annual report, including the reason why it was not performed (e.g., lack of suitable subject for meeting date, business reasons). Because the information supporting approval of a live case presentation may vary, prior approval may be needed to conduct each live case presentation, even if one was granted previously. Sponsors are encouraged to consult with the FDA review Division in a pre-submission to discuss their plans for live case presentations before submitting an IDE application or supplement to an IDE application.

Also, as described above, summary information of those subjects who participate in live case presentations should be collected and reported in a separate section in the sponsor's annual progress reports, in the final study report to the reviewing IRB and FDA, and in any future marketing submission(s). Clinical outcomes should be analyzed separately and summarized descriptively, unless a statistically valid comparison can be made with the rest of the study cohort.

VI. Conclusion

This guidance provides recommendations as to the type of information that FDA believes will be useful in reviewing IDE applications containing a request for a live case presentation. By proactively anticipating live case presentations and prospectively identifying the study parameters around such live case presentations, the Agency believes that protections to human research subjects will be improved, burdens to the sponsor and the Agency will be minimized, and study validity related to live case presentations using investigational devices will be assured.

Attachment A. Suggested elements of a request to include live case presentations

The following is a list of recommended items to include, as applicable, in an original IDE application or a supplement to an IDE application when requesting live case presentations for clinical investigations of significant risk devices.

General Information

The sponsor should provide:

- A detailed rationale for why the live case presentation is being requested, including an explanation of the status of subject enrollment and investigator recruitment;
- The name, date, and location of the event (if known) where the live case presentation will be broadcast and investigational site where the procedure will be conducted;
- A discussion of how the live case nature of the procedure will affect the scientific soundness of the study or necessitate any revisions of the protocol and planned statistical analysis;
- Justification for the requested number of live case presentations;
- Criteria for how potential subjects will be selected;
- The potential effects of subject selection for live case presentations on unmasking investigator and subject;
- Treatment assignment and the effect on the randomization schedule;
- Information about the potential for selection bias and how this will be minimized;
- Justification for study sample size. As live case presentation subjects may be excluded from the primary study analyses, the requested number of subjects may need to be adjusted to account for live case presentation(s);
- A revised risk analysis that includes a discussion of the increased risks posed by the live case presentation; and
- A statement that the live case presentations are being conducted at previously approved investigational sites by investigators who have signed an agreement with the sponsor pursuant to 21 CFR 812.43(c) and who are currently participating in the study.

Informed Consent

The sponsor should provide an informed consent document that complies with 21 CFR part 50. The informed consent for a live case presentation should describe, where applicable:

- Whether the procedure will be recorded for future viewing and/or broadcast to an audience during the conduct of the procedure;
- That there is no additional direct benefit to the subject for participating in the live case presentation beyond the benefits of the clinical investigation, if any;
- That it is not known whether participating in a live case presentation will affect clinical outcome compared to subjects who do not participate;
- Any additional or increased risks posed by performing the procedure as a live case presentation, such as risks posed by increased anesthesia and/or procedure

time, compared to the procedure not being performed as a live case presentation (see previous discussion under "Risk Analysis");
- Any additional or increased risks related to subject confidentiality that may occur as a result of participation in the live case presentation, such as privacy concerns related to the live case broadcast, and subsequent distribution and/or use of a video or other type of stored media of the procedure; and
- Whether additional follow-up and evaluation may be warranted as a result of the subject's participation in a live case presentation and how such follow-up and evaluation may be different compared to the procedure not being performed as a live case presentation.

If live case presentations involve children, assurance of the following additional safeguards for the protection of the rights, safety, and welfare of the children should be included in the request:

- The added risks of being involved in a live case presentation will involve no more than minimal risk to the enrolled child;
- Permission of the parent or guardians will be obtained as set forth in 21 CFR 50.55; and
- Adequate provisions will be made for soliciting the assent of the child as set forth in 21 CFR 50.55.

Reporting and Analysis Plans

The sponsor should provide:

- A detailed description of proposed data collection and reporting for subjects participating in a live case presentation. Sponsors should address whether data collection and reporting will be according to the IDE protocol, and if not, provide a detailed description of (and justification for) any anticipated changes to the protocol. Subject follow-up and evaluation should be specifically discussed, and should be the same as that specified in the IDE protocol, unless the patient's condition warrants additional follow-up and evaluation; and
- An analysis plan for the live case presentations that include all relevant observations, including adverse device effects (whether anticipated or unanticipated), and specifying how the live case presentation data will be stratified and included in safety and/or efficacy analyses.

Information Concerning IRB Review

The sponsor of an investigation should provide:

- A statement that it will obtain IRB approval before adding a live case presentation to the clinical study; and
- A statement that the clinical outcomes of subjects treated in live case presentations will be included and analyzed with those of the other study subjects according to the pre-specified statistical analysis plan, as well as, analyzed and reported separately when included in reports to the FDA and as required by the IRB.