STANDARD OPERATING PROCEDURE

OBJECTIVE/SCOPE

To ensure that the National Marrow Donor Program (NMDP) Institutional Review Board (IRB) has established processes for expedited review, emergency review, and for determining when studies are exempt from regulation.

MATERIALS

1. Initial Review Determination (Exempt) Form

SAFETY

Not applicable

DEFINITIONS

1. **Annual Status Report:** An annual report of study status and subject enrollment for studies eligible for expedited review in accordance with 2018 Common Rule Requirements.

2. **Blood and Marrow Transplant Clinical Trials Network (BMT CTN):** Conducts large multi-institutional clinical trials addressing important issues in hematopoietic cell transplantation thereby furthering understanding of the best possible treatment approaches.

3. **Classified research:** Research that has a security classification established by an authorized agency of the federal government.

4. **Common Rule:** A Federal Policy for the Protection of Human Subjects codified in separate regulations by the Department of Health and Human Service (DHHS) and other Federal departments and agencies.
   - 4.1. **2018 Revised Common Rule Requirements:** Revised Federal Policy for the Protection of Human Subjects (Revised Common Rule) requirements effective on January 21, 2019.
   - 4.2. **Pre-2018 Common Rule Requirements:** Federal Policy for the Protection of Human Subjects (Common Rule) requirements originally published on June 18, 1991 and effective until January 21, 2019.

5. **Center for International Blood and Marrow Transplant Research (CIBMTR):** A research collaboration between the National Marrow Donor Program(NMDP)/Be The Match and the Medical College of Wisconsin.

6. **Expedited review:** A procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the NMDP IRB.

7. **Exempt from regulation:** Research that qualifies for exemption from the requirements of 45 CFR 46.104(d)(1)-(8) or 21 CFR 56.104(c)-(d).

8. **IRBManager:** Web-based system for IRB application submission, IRB application review, and management of IRB-related study records.

9. **Limited IRB Review**: A type of review process required for exempt categories under 45 CFR 46.104 (d)2(iii), (d)3(i)(c), and (d)7 and 8.

10. **Research protocol:** General term used to refer to a study proposal, research project, concept paper, etc.

11. **Resource for Clinical Investigations in Blood and Marrow Transplantation (RCI BMT):** A team within the NMDP dedicated to advancing the field of hematopoietic cell transplantation and cellular therapy by providing trial management, survey research, and data management services for multi-center trials.

RESPONSIBILITIES

1. **NMDP IRB Administrator**
   - Determine if proposed research qualifies as exempt from regulation, and whether the exempt research meets the ethical standards in *The Belmont Report* and criteria for participant protection as outlined in 45 CFR 46.

2. **NMDP IRB Chair**
   - Conduct expedited reviews or designate another IRB member to conduct the review.
   - Determine if proposed research qualifies as exempt from regulation, and whether the exempt research meets the ethical standards in *The Belmont Report* and criteria for participant protection as outlined in 45 CFR 46.

3. **NMDP IRB Members**
   - Conduct expedited reviews of adding study sites on multi-site protocols.

4. **NMDP IRB Staff**
   - Determine whether or not an expedited review process can be used for proposed research.

PROCEDURE

1. **Expedited review**

1.1. The U.S. Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) have established a list of categories of research that may be reviewed by the NMDP IRB through an expedited review process. This list is published in the Federal Register and is amended as necessary. The NMDP IRB may use an expedited review process for any research study that 1) falls into one of the categories of research approved for expedited review and 2) does not involve more than minimal risk. These categories are listed below.

1.1.1. **Category 1:** Clinical studies of drugs and medical devices only when one of the following conditions is met:

1.1.1.1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

1.1.1.2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

1.1.2. **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1.1.2.1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period, and collection may not occur more frequently than 2 times per week; or

1.1.2.2. from other adults and children, considering the age, weight, and health of the participant, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.

1.1.2.3. **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

1.1.2.3.1. Hair and nail clippings in a nondisfiguring manner;

1.1.2.3.2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

1.1.2.3.3. Permanent teeth if routine patient care indicates a need for extraction;

1.1.2.3.4. Excreta and external secretions (including sweat);

1.1.2.3.5. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

1.1.2.3.6. Placenta removed at delivery;

1.1.2.3.7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

1.1.2.3.8. Supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
1.1.2.3.9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
1.1.2.3.10. Sputum collected after saline mist nebulization.

1.1.2.4. **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
1.1.2.4.1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
1.1.2.4.2. Weighing or testing sensory acuity;
1.1.2.4.3. Magnetic resonance imaging;
1.1.2.4.4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography;
1.1.2.4.5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

1.1.2.5. **Category 5:** Research involving materials (data, documents, records, or specimens) that:
1.1.2.5.1. have been collected for nonresearch purposes (such as medical treatment or diagnosis), or
1.1.2.5.2. will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
1.1.2.5.2.1. NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human participants.

1.1.2.6. **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

1.1.2.7. **Category 7:** Research on individual or group characteristics or behavior including, but not limited to:

1.1.2.7.1. Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or

1.1.2.7.2. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

1.2. For NMDP/CIBMTR studies that receive funding from the Department of the Navy, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

1.3. An expedited review process may also be used for minor changes in previously approved research during the time in which the approval was authorized if the changes do not in any way increase the risk to subjects. For example, an amendment to a research protocol that decreases the amount of blood to be collected for a specified test could be approved through an expedited review process.

1.4. An expedited review process may also be used for continuing review if the research falls into one or more of the following regulatory categories that allow continuing review using the expedited procedure.

1.4.1. **Category 8:** Continuing review of research previously approved by the convened IRB as follows:

1.4.1.1. the research is permanently closed to the enrollment of new participants;

1.4.1.2. all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or

1.4.1.3. where no participants have been enrolled and no additional risks have been identified; or

1.4.1.4. where the remaining research activities are limited to data analysis.

1.4.2. **Category 9:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1.5. An expedited review process may not be used where identification of the subjects and/or their responses would reasonably place them at risk of

criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

1.6. An expedited review process may not be used for classified research.

1.7. The determination to use an expedited review process will be made at the discretion of the NMDP IRB staff upon pre-review of incoming materials. The IRB Administrator may be consulted for such determinations if needed.

1.8. Documentation of the expedited review determination will include the specific permissible category.

1.8.1. If an expedited reviewer determines that the research appearing on the expedited review list is more than minimal risk, the rationale for this determination must be documented.

1.8.2. For FDA-regulated clinical investigations, the NMDP IRB will continue to comply with FDA's regulations at 21 CFR 56.110(b) and use the 1998 list for FDA-regulated clinical investigations

1.9. The following process will be used for an expedited review:

1.9.1. The NMDP IRB Chair shall review initial reviews, continuing reviews, and study-level minor amendments to previously approved research.

1.9.1.1. The NMDP IRB Chair, at his/her discretion, may designate one or more members of the NMDP IRB to perform such expedited reviews in the following situations:

1.9.1.1.1. If the NMDP IRB Chair is unable to perform the expedited review in a timely manner.

1.9.1.1.2. If the NMDP IRB Chair feels the expertise of another IRB member(s) is better suited for review of a particular type of study.

1.9.1.1.3. If the NMDP IRB Chair has a financial or other conflict of interest pertinent to the research protocol or Principal Investigator.

1.9.1.1.3.1. If the designated IRB member(s) has a financial or other conflict of interest pertinent to the research protocol or Principal Investigator, he/she must disclose the conflict of interest so that another IRB member may be appointed to perform the expedited review.

1.9.1.2. To qualify as an expedited reviewer for a particular study, the IRB member, according to the judgment of the IRB Chair, must have the experience and education required to conduct expedited review for that type of study.

1.9.2. The reviewer(s) will receive all study documentation (Refer to SOP #: S00040, NMDP IRB Protocol Review)

1.9.3. The reviewer(s) will conduct the review according to procedures in SOP # S00040, NMDP IRB Protocol Review.

1.9.4. The reviewer(s) shall exercise the full authority of the NMDP IRB, except that they cannot disapprove the study. If the reviewer(s) does not find it acceptable to approve the study or amendment, the study or amendment will go before the full NMDP IRB for a non-expedited review.

1.9.4.1. The reviewer(s)' action shall be documented in IRBManager.

1.9.5. If the reviewer(s) approves the study with stipulations, but the investigator does not accept the stipulations, the study will go before the full NMDP IRB for review.

1.9.6. If the study is approved by the reviewer(s), the full NMDP IRB will be informed of the expedited review by including a summary of the study, or a summary of the amendment to the previously approved research, on the agenda for the next regularly scheduled IRB meeting.

1.9.7. The study summary will also include any specific findings regarding informed consent and vulnerable subjects. (Refer to SOP#: S00047, NMDP IRB Record Management)

1.9.8. The expedited review process shall follow the procedures set forth in SOP # S00040, NMDP IRB Protocol Review regarding the following:

1.9.8.1. Determination of review interval

1.9.8.2. Further review and approval of NMDP IRB actions within the NMDP

1.9.8.3. How Investigators should respond to stipulations and how that response is reviewed

1.9.8.4. When continuing reviews shall be conducted

1.9.8.4.1. NOTE: Continuing review is not required for studies initially reviewed by expedited procedures under the 2018 Revised Common Rule Requirements that are not regulated by the FDA, unless the reviewer documents explicit justification why continuing review would enhance protection of research subjects. Instead, the investigators will be required to submit an Annual Status Report.

1.9.8.5. Consequences of the Investigator not providing continuing review information to the IRB, or of the IRB not reviewing and approving a research study by the date of IRB expiration

1.9.8.6. Review of changes in approved research

1.9.8.7. Completion of a study

1.9.9. The NMDP IRB Chair has designated all members of the NMDP IRB to be capable of conducting expedited reviews of adding study-sites to multi-site protocols that have already been reviewed by the NMDP IRB.

2. Annual Status Report

2.1. For studies initially reviewed by expedited procedures under the 2018 Revised Common Rule Requirements, investigators will complete an annual report with information about study status and subject enrollment, including recipients and donors. At that time, the investigators will also have an option

to submit amendments that have not yet been implemented or close the study.

2.2. Annual Status Reports are reviewed by administrative procedures unless there is a change in the study status requiring an IRB review.

3. Emergency exemption

3.1. In the case of volunteer hematopoietic cell donors, who are by definition healthy research subjects, there is no justification for emergency use of an investigational drug, biologic, or investigational device.

3.2. There are, however, cases where a volunteer donor is asked to make a donation on an urgent basis for a recipient enrolled in a research protocol that also requires NMDP IRB review and approval for the donor to participate. In these cases, a quorum of the NMDP IRB membership will be convened to review the research protocol on an urgent basis. The urgent review process will be the same as that outlined in SOP #: S00040, NMDP IRB Protocol Review.

3.2.1. If a quorum of the NMDP IRB membership is not able to convene for an urgent review, the donation may be done as an emergency exemption, if approved by the NMDP Vice President/Senior Medical Director of Medical, Quality, & Regulatory Services or his/her designee. In the case of an emergency exemption the donor-patient pair must not be considered research subjects, and any resulting data must not be included in any subsequent publications or presentations of research.

3.2.2. In an emergency exemption, donor consent will be obtained, unless the legal and regulatory requirements for an exception to obtain consent are met.

3.3. The transplant center's institutional policies and procedures for the emergency use of an investigational drug, biologic, or investigational device must be followed for a patient at that transplant center to access in an emergency situation an investigational product offered through a BMT CTN or CIBMTR/NMDP/Be The Match research protocol.

4. Exemption from regulation

4.1. Any research study involving human subjects that falls into one of the research categories listed in 45 CFR 46.104(d)(1)-(8) is exempt from regulation.

4.1.1. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. [45 CFR 46.104(d)(3)(ii)]

4.1.2. FDA-regulated research cannot be exempt.

4.1.3. NMDP will follow the applicable Federal regulations in determining exempt status of research involving children as participants.

4.2. Exemption categories that may be utilized by NMDP:

4.2.1. **Category 2**

4.2.1.1. The research only involves interactions involving one or more of the following:

4.2.1.1.1. Educational tests (cognitive, diagnostic, aptitude, achievement).

4.2.1.1.2. Survey procedures.

4.2.1.1.3. Interview procedures.

4.2.1.1.4. Observation of public behavior (including visual or auditory recording).

4.2.1.2. One of the following conditions are met:

4.2.1.2.1. The information obtained is recorded in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.

4.2.1.2.1.1. When the research involves children, this exemption only applies to educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

4.2.1.2.2. Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

4.2.1.2.2.1. When the research involves children, this exemption only applies to educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

4.2.1.2.3. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identfiers linked to the participants, and an IRB conducts a limited IRB review of the research, and determines whether there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data

4.2.1.2.3.1. This condition cannot be applied when research is subject to Subpart D.

4.2.1.3. The research does not involve prisoners, except for research aimed at involving a broader participant population that only incidentally includes prisoners.

4.2.1.4. The research is not regulated by the FDA.

4.2.2. **Category 3**

4.2.2.1. Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal

or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection. Benign behavioral interventions are:

4.2.2.1.1. Brief in duration.
4.2.2.1.2. Harmless.
4.2.2.1.3. Painless.
4.2.2.1.4. Not physically invasive.
4.2.2.1.5. Not likely to have a significant adverse lasting impact on the participants.

4.2.2.2. The researcher has no reason to think the participants will find the interventions offensive or embarrassing.

4.2.2.3. At least one of the following criteria is met:

4.2.2.3.1. The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through indentifiers linked to the participant; or

4.2.2.3.2. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or

4.2.2.3.3. If the information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, an IRB conducts a limited IRB review and determines, when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

4.2.2.4. If the research involves deception of participants regarding the nature or purposes of the research, the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4.2.2.5. The research does not involve prisoners, except for research aimed at involving a broader participant population that only incidentally includes prisoners.

4.2.2.6. The research is not regulated by the FDA.

4.2.3. **Category 4**

4.2.3.1. Secondary research for which consent is not required, that uses identifiable private or identifiable biospecimens, if at least one of the following criteria are met:

4.2.3.1.1. The identifiable private information or identifiable biospecimens are publicly available.

4.2.3.1.2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects,

the investigator does not contact the subjects, and the investigator will not re-identify subjects.

4.2.3.1.3. The research involves only information collection and analysis involving the researcher's use of identifiable health information regulated under HIPAA for the purposes of "health care operations" or "research" or "public health activities and purposes" as defined in HIPAA.

4.2.3.1.4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 or Privacy Act of 1974, 5 U.S.C. 552a., and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501.

4.2.3.2. The research does not involve prisoners, except for research aimed at involving a broader participant population that only incidentally includes prisoners.

4.2.3.3. The research is not regulated by the FDA.

4.3. The IRB Chair or IRB Administrator will determine if proposed research is exempt from regulation. Exemption determinations may not be made solely by the researcher or someone with a conflict of interest in the research.

4.3.1. Should the IRB Administrator have an apparent or real conflict of interest regarding the study, the determination of exemption will be made by the IRB Chair.

4.3.2. Should the IRB Chair have an apparent or real conflict of interest regarding the study, the determination of exemption will be made by the IRB Administrator.

4.4. The IRB Chair or IRB Administrator will determine whether the exempt research meets the ethical standards in *The Belmont Report* and criteria for participant protection as outlined in 45 CFR 46.

4.4.1. This criteria includes, but is not limited to, the following:

4.4.1.1. The research involves no more than minimal risk to participants.

4.4.1.2. Selection of participants is equitable.

4.4.1.3. There are adequate provisions to maintain the confidentiality of data and the privacy of participants.

4.4.1.4. The participants will be informed:

4.4.1.4.1. that the activity involves research,

4.4.1.4.2. of the research procedures,

4.4.1.4.3. that participation is voluntary,

4.4.1.4.4. of the investigator's name and contact information.

4.4.2. Should the IRB Chair or IRB Administrator feel that the exempt research raises ethical concerns or requires measures to protect participants, modifications to the research may be required prior to a final determination of exempt status.

4.5. Determinations of exemption will be documented on the Initial Review Determination (Exempt) Form

4.5.1. Documentation of the exemption will include the exemption category listed in 45 CFR 46.104.

4.5.2. Documentation of the exemption will be kept on file at the NMDP.

4.5.3. The Initial Review Determination (Exempt) Form will be sent to the Principal Investigator.

4.5.3.1. The Initial Review Determination (Exempt) Form will include a directive that any changes to the study must be reviewed by the NMDP IRB prior to implementation to determine whether the research continues to qualify for exemption from regulation.

5. Limited IRB Review

5.1. Limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). In addition to a limited IRB review, the procedures for determining exemption as described in this SOP will be followed for these exempt categories, with the exception that the IRB Chair must conduct the limited IRB review.

5.2. Research eligible for limited IRB review is deemed to be no more than minimal risk.

5.3. For the purposes of conducting the limited IRB review, the reviewer must make a determination that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

5.4. For the purposes of conducting the limited IRB review required by §46.104(d)(7) and (d)(8), the reviewer must make a determination that the broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR 46.116(a)(1)-(4), (a)(6), and (d) and that the broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with 45 CFR 46.117.

5.5. IRB members conducting limited IRB review may not disapprove the research.

5.6. Continuing review is not required for studies that qualify for a limited review.

5.7. NMDP retains the authority to suspend or terminate IRB approval of research approved with a limited review.

REFERENCES

1. 21 CFR 56
2. 45 CFR 46 Subparts A, B & D
3. SOP#: S00040, NMDP IRB Protocol Review
4. SOP#: S00047, NMDP IRB Record Management
5. *The Belmont Report*
6. OPRR Guidance on 45 CFR 46.101(b)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs
7. Office for Human Research Protections (OHRP) Guidance on Expedited IRB Review – Categories
8. Department of Defense Instruction (DoDI) 3216.02, 6.b

Revision History

Revision	Brief Description of Revision
S00041 08/17/2001	New SOP
S00041 version 2.0	Annual Review: Added Exempt from Review definition, added sections 1.5.3 – 1.5.6
S00041 version 3.0	Added an Applicable Reference Document. Added section 3.4. Formatting changes.
S00041 rev. 4	Put into new SOP format. Changed language from “exempt from review” to “exempt from regulation.” Added applicable reference documents. Added 1.3. Revised 1.4. Added 1.6.1.1 and sub-points. Added 1.6.3, 1.6.4.1, 1.6.5, 1.6.8 and sub-points. Revised 3.1, 3.2 and their sub-points. Added 3.3, 3.4 and their sub-points.
S00041 rev. 5	Added definition of Research protocol. Added 1.4, 1.7.1.2, 2.3.1, 3.3.1.4.1. Clarifications made to several sections. Added Reference Document on OHRP Guidance on Expedited Review Categories.
S00041 rev. 6	Added 1.1.1. Added DoDI reference doc.
S00041 rev. 7	Revised section 3.2 and 3.3 to state that the IRB Chair **or** IRB Administrator (not both) will make exemption determinations.
S00041 rev. 8	Added section 3.1.1 stating that FDA-regulated research cannot be exempt.
S00041 rev. 9	Added Materials. Added definitions for CIBMTR and RCI BMT. Added Responsibilities section. Reworded 1.5 to state that the IRB Administrator may be consulted if needed. Added 2.4 regarding emergency exemptions for recipients.
S00041 rev. 10	Added definitions. Updated CFR reference for exemption requirements. Added 1.6.1 and 1.6.2. Added section 2 on Annual Status Report. Revised 3.3. Added section 5 on Limited IRB Review.
S00041 rev. 11	Added definition of IRBManager. Added Responsibility of IRB

	Members. Added sect 1.7.9. Removed references to Documentation of IRB Review/Approval form.
S00041 rev. 12	Added definition for classified research. Added categories of Expedited review in sections 1.1 and 1.4. Added 1.6. Clarified 1.9.8.4.1. Added 4.1.1. Added 4.2 with exemption categories. Added clarification to 4.3. Deleted 5.4.1 as it is no longer true. Clarified 5.1 and procedures used for Limited IRB review. Added 5.2., 5.5, 5.6, and 5.7.

ADDENDA

Not applicable