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Institutional Review Board Written Procedures: Guidance for Institutions and IRBs Written Procedures Checklist — Excerpt

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Activity	Written Procedure? Check yes if the IRB or institution/HRPP has a written procedure on this topic, no if it does not, and *N/A* if not applicable.			Notes
	Yes	No	N/A	
Additional Topics the Institution/IRB May Consider:				
Scope and Authority				
1. The development and scope of the written procedures (e.g., who is responsible for preparing and maintaining them, including writing, revising, and approving; how often they are reviewed and updated, who they apply to; what happens if they are not followed).				
2. The institutional authority under which the IRB is established and authorized, and the independence afforded the IRB to carry out its duties.				
3. The ethical principles that govern the IRB in assuring that the rights and welfare of human subjects are protected.				
4. Important regulatory definitions that guide the IRB's review processes and procedures (e.g., the definition of research, clinical investigation, human subject, minimal risk).				

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5. Other relevant federal regulations that may apply to human subject research (e.g., Health Insurance Portability and Accountability Act regulations, Department of Defense regulations).				
6. Which institutional office(s) or official(s), if any, is responsible for further review and approval, or disapproval, of research that is approved by the IRB.[1]				
7. The IRB's relationship to the administration of the institution, the other committees and department chairpersons within the institution, the research investigators, other institutions, and the regulatory agencies.				
IRB Membership				
1. The number of members on the IRB.[2]				
2. Ensuring diversity in IRB membership (e.g., representation of both genders, multiple professions, scientific and nonscientific members, nonaffiliated members).[3]				
3. Selecting and appointing the IRB chairperson, the members, and alternate members if any, including: The length of term or service, general description of duties, attendance requirements, performance evaluation, including removal if necessary. The qualifications of the IRB chairperson, members and any alternate members.[4] The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated.[5]				

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4. Defining what constitutes a conflicting interest for the IRB chairperson, members, and alternate members, and managing any such conflicting interest, including recusal from a meeting to ensure that a chairperson, member, or alternate member with a conflicting interest does not vote or count towards the quorum.[6]				
5. Training and education provided to the IRB chairperson, IRB members, alternate members, administrative support staff, and investigators.				
IRB Functions and Operations				
1. Determining whether a study is subject to IRB review (e.g., what types of studies must be reviewed, which regulations apply, who makes the determination).				
2. Determining which HHS-conducted or -supported research studies qualify as exempt from the HHS regulations, including who makes the determination.				
3. Implementing cooperative IRB review arrangements, when applicable, such as joint review, reliance on the review of another qualified IRB, or similar arrangements aimed at avoiding duplication of effort.[7]				
3. Process for reporting the emergency use of an FDA-regulated test article to the IRB.[8]				
4. The use of consultants by the IRB;[9] including a description of the process to identify the need for a consultant, to choose a consultant, and the consultant's participation in the review of research.				

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5. Identifying and managing an investigator with a conflicting interest.				
6. Determining the applicability of state and local laws.[10]				
7. Tracking study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to follow if IRB approval lapses.				
8. Handling subject complaints, problems, concerns and questions about rights as a research subject.				
9. Administrative support staff duties.				
10. Keeping the IRB informed of study completion and close out to ensure record retention in compliance with 45 CFR 46.115(b) and/or 21 CFR 56.115(b) .				
11. Registering the IRB and maintaining IRB registration[11] via the HHS Internet-based registration system.[12]				
12. Providing access to information about IRB requirements and written procedures (e.g., posting the information on a website accessible to the investigators, sponsors, and others).				
13. Contingency plans for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the study (e.g., the IRB closes, suffers loss due to fire, natural disaster).				

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IRB Records				
1. Maintaining records required to be retained,[13] and other records (e.g., IRB member training records).				
2. Where records are stored (e.g., on site, off-site archives), and the format for record storage (e.g., hard copy, electronic or both).				
3. Preparing and maintaining minutes of IRB meetings.[14]				
4. Retaining records for at least 3 years after completion of the research, and ensuring records are accessible for inspection.[15]				