

Appendices to the Policies and Procedures of the Harvard Faculty of Medicine CHS*

1. Statement of Policies and Procedures Governing the Use of Human Subjects in Research
2. Federalwide Assurance Approval (terms)
3. Harvard University Statement of Values
4. HMS Principles and Procedures for Dealing with Allegations of Faculty Misconduct
5. Policy on Conflicts of Interest and Commitment
6. Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators
7. Policy Statement Regarding Application of Harvard University Conflict of Interest Policies to the Granting of Licenses
8. Harvard Policies Relating to Start-Up Ventures
9. Components of the Institution - *available upon request*
10. Institutional Official Appointment from the Dean - *available upon request*
11. Harvard Ethics Training in Human Research (HETHR)
12. CHS Website
13. Reviewer Sheet - FC
14. Reviewer Sheet - Expedited
15. Reviewer Sheet - Exempt
16. Reviewer Sheet: Addendum - Vulnerable Populations
- 16a. Reviewer Sheet Addendum – Devices
- 16b. Reviewer Sheet Addendum – Drugs
17. Job Descriptions of the CHS Staff - *available upon request*
- 17a. Performance Planning and Review Resource Guide
18. CHS Application and Instructions
- 18a. Translation Attestation Form
19. Form A
20. Form B
21. Personnel Roster
- 21a. Form E
22. Use of Coded Private Information or Biological Specimens Form

* *All items listed are hyperlinks to information available on the internet.*

- 22a. Determination of Human Subjects Research
23. Not Human Subjects Research (example letter) - *available upon request*
24. Specimens or Data Not Human Subjects Research (example letter) - *available upon request*
25. Detailed Disclosure Statement
26. Disclosure Summary
27. Notification of Exemption (example letter) - *available upon request*
28. Report on Action-Expedited initial review (example letter) - *available upon request*
- 28a. Review Confirmation Sheet (FC and Expedited) – *available upon request*
29. Responsibilities of the Investigator - *available upon request*
30. Report on Action-Full Committee initial review (example letter) - *available upon request*
31. Continuing Review Application and Instructions
32. Report on Action-Full Committee continuing review (example letter) - *available upon request*
33. Report on Action-Expedited continuing review (example letter) - *available upon request*
34. File Closure Form
35. Amendment Request Form
36. Report on Action-Full Committee amendment review (example letter) - *available upon request*
37. Report on Action-Expedited amendment review (example letter) - *available upon request*
38. Amendment Acknowledgement Letter for Exempt Studies (example letter) - *available upon request*
39. IRB Review Designation Request Form
40. Designation Letter (example letter) - *available upon request*
41. Confirmation of File Closure (example letter) - *available upon request*
42. Material Transfer Agreement (example form)
43. Clinical Trials Agreement (example form) - *available upon request*
44. Student Letter of Participation (example letter) - *available upon request*
45. Harvard University Policy and Procedures-Human Subjects Processing Payments
46. Harvard University Research Administration-information on HIPAA
47. School of Dental Medicine Research Website
48. Request for HIPAA Waiver
49. Rules Governing the Participation of Medical Students as Experimental Subjects in Research Studies

- 49a. Harvard University Researchers' Guide for Use of Controlled Substances
- 49b. Form C
- 50. Investigational Drug and Biologic Accountability Log - *available upon request*
- 50a. Form D
- 51. Investigational Device Accountability Log - *available upon request*
- 52. Unanticipated Problem/Adverse Event Form
- 53. Guidelines for Investigators in Clinical Research
- 55. Sample Consent Form for Adults
- 56. Center or Program Grant Form
- 57. Non-Compliance Report Form