Registry and Repository Start-up Guide

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Step by step start-up guide for registries and repositories

This guide asks 54 questions about things to consider when creating a registry or repository. This guide is divided in 3 sections: What will you collect? How will you collect it? What else is needed? We hope this guide will help you in your registry and repository planning.

What will you collect?

Area of focus

1. Will your registry or repository focus on a specific condition? ☐ Yes ☐ No

2. If yes, please describe:

3. Which statement best describes your organization's priorities?

☐ Clinical information is more important than physical samples
☐ Clinical information and physical samples are equally important
☐ Physical samples are more important than clinical information

4. Will you create a registry to collect medical/clinical information? ☐ Yes ☐ No

5. If yes, what information will you collect?

☐ Medical information
☐ Participant demographics
☐ Participant lifestyle information
☐ Family history
☐ Genetic information
☐ Diagnosis/treatment information
☐ Pedigree information
☐ Information on physical samples
☐ Other

6. Will you collect physical samples? ☐ Yes ☐ No

7. If yes, what physical samples will you collect?

☐ Blood for DNA extraction
☐ Buccal swab for DNA extraction
☐ Tissue (frozen)
☐ Tissue (formalin)
☐ Cell blocks

- ☐ Cell Lines
- ☐ Other

Study design

8. Will you collect data or samples from any of the following?

- ☐ Cases
- ☐ Controls
- ☐ Affected families
- ☐ Trios
- ☐ Sib-pairs
- ☐ Children
- ☐ Vulnerable populations
- ☐ Other

9. What is the inclusion/exclusion criteria for those described above?

10. What is your collection goal? (This will affect funding and resources.)

11. What do the following advisors/ experts in the field recommend for study design?

- ☐ Scientific advisory board
- ☐ Medical advisory board
- ☐ Researchers who will use samples
- ☐ Clinicians
- ☐ Other advocacy organizations with registries/repositories

12. How will researchers use your samples? (e.g. DNA/genomics analysis, RNA expression, etc).

Ownership and access

13. Who will own your data and/or samples?

14. Who will govern/make decisions about your collection?

15. Who will determine access to data and/or collected samples?

16. Who will have access to data and/or collected samples?

17. Do you have material transfer agreements in place?

How will you collect data and/or samples?

Regulatory compliance

18. Who are the principal investigators (PIs)?

19. Who will develop the protocol?

20. Who will submit the IRB application? Where will you submit the application?

21. How will you obtain informed consent? Who will obtain the informed consent?

22. How will you protect participants' information and privacy?

Operations and resources

23. How much will your collection cost to build? To maintain?

24. How will your collection be funded?

25. Who will manage day-to-day operations of your collection?

26. Are systems in place to manage the administrative aspects of a research study?

27. How will you recruit participants?

28. How will you retain participants?

29. Who will help you collect data and/or samples?

30. Are protocols in place for data and/or sample collection? Who will help you design protocols?

31. How will you distribute data and/or samples?

32. How will this program impact other parts of your organization?

Registry considerations

33. Where will the data be stored?

34. Who will design the questionnaire? What format will the questionnaire be?

35. Is there controlled language/ vocabulary?

36. Who will complete the questionnaire? How often will the questionnaire be completed?

37. What steps are in place for quality control?

38. Who is responsible for technology and security? What back-up systems are in place?

Repository considerations

39. Where will your samples be physically located?

40. Who will assemble and send kits to donors?

41. Who will receive completed kits?

42. Who is responsible for sample processing? For sample storage?

43. Are appropriate protocols in place for sample processing, storage and distribution?

44. Who is responsible for sample integrity/security? What back-up systems are in place?

What else do you need?

Public relations and materials

45. How will you announce your collection to your community?

46. How will you announce your collection to the medical and research community?

47. What materials will you develop?
- ☐ Web site
- ☐ Brochures
- ☐ Features in newsletter/ magazine
- ☐ E-newsletters
- ☐ Direct mail pieces
- ☐ Incentive materials (stickers, pens, note cards, post its)

48. What is your recruitment strategy?
- ☐ Web site
- ☐ Member communications
- ☐ Outreach events
- ☐ Medical professionals
- ☐ Media (press releases and NAPS release)

49. What is your retention strategy?
- ☐ Incentive mailings
- ☐ Timely updates (member communications and quarterly updates)
- ☐ Event cards (Thank you card, Birthday card, New Year's card)

Making samples available to researchers

50. How will you make your collection available to researchers?

51. Do you have a biobank oversight committee?

52. How will you attract new researchers to your collection?

53. How can you promote collaborative research?

54. How will you drive the research agenda?