SURVEY

Clinical-Research Interface Project

CSER Consortium (Final)

INTRODUCTION

This is a survey asking questions about how the line is being drawn and should be drawn between research and clinical care in genomic sequencing. We are asking CSER U-award projects to respond to the questions below, so that our author group can compare and aggregate information across sites. We are trying to understand how this question arises in CSER studies, the potential challenges, and how different CSER sites are addressing them.

We are asking the PI at each site to determine the best respondent(s) from each site. One response option you may want to consider is to convene a group of project investigators and other personnel involved in your project, with one person acting as scribe to write group answers.

Please convey your response sheets to Wylie Burke (University of Washington) (wburke@u.washington.edu) or Susan Wolf (University of Minnesota) (swolf@umn.edu), the leaders of this project. We will remove the names of any individuals and your institution(s), as well as the name of your project, before sharing your answers with the author group. In our publication(s), no individual, institution, or project will be identified with any particular answer or result.

Please note that this survey does not represent human subjects research (as determined by consultants at the University of Washington and the University of Minnesota) because we are sharing information among professionals within a research collaboration. If you have any questions or concerns, please contact Wylie or Susan.

Our author group is based in the CSER Consortium with some added collaborators; the group is: Susan M. Wolf, JD, and Wylie Burke, MD, PhD, chairs; Laura Amendola, MS, CGC (University of Washington); Jonathan Berg, MD, PhD (UNC, Chapel Hill); Wendy Chung, MD, PhD (Columbia); Ellen Clayton, MD, JD (Vanderbilt); Robert Green, MD, MPH (Brigham & Women's, Harvard); Julie Harris-Wai, PhD, MPH (Kaiser Permanente Division of Research); Gail Henderson, PhD (UNC, Chapel Hill); Gail Jarvik, MD, PhD (University of Washington); Steven Joffe, MD, MPH; Barbara Koenig, PhD (UCSF); Lisa Lehmann, MD, PhD, MSc (Brigham and Women's, Harvard); Amy McGuire, JD, PhD (Baylor); Pearl O'Rourke, MD (HealthPartners); Carol Somkin, PhD (Kaiser Permanente Division of Research); and Benjamin Wilfond, MD (Seattle Children's Hospital, University of Washington).

We greatly appreciate your help! Your responses will help advance thinking on the research/clinical interface in genomics.

PRELMINARY INFORMATION:

Which CSER project are you telling us about?

What is today's date?

Who is responding to this survey? If multiple project personnel are contributing to the answers below, please indicate how many people are involved in responding and identify them by project role (e.g., PI, Co-I, Genetic Counselor, Nurse).

If we would like to clarify any answers below, is there someone in your response group who we could contact? If so, **please provide that person's name and contact information**.

RESEARCH-CLINICAL INTERFACE AT YOUR CSER SITE

1. What professionals are involved in implementing your CSER project?

   a. Are clinicians involved your CSER study?

   If yes, please check all activities that apply and indicate which clinical specialties are involved in each:

   __Referral of participants to study

   __Participated in study design

   __Serve as study participants themselves

   __Provide return of results

   __Deliver care after genomic testing as part of the study process

   __Other

   b. Are other professionals involved in your study (e.g., policy leaders, organizational leaders, etc.)

   If yes, please specify

2. Do any research procedures take place in a clinical setting where participants are getting health care unrelated to research? (yes or no)

   If yes, please list the procedure(s) and setting(s)

3. Have you noted any role ambiguity – for example, members of research team being asked clinical care questions that should have been directed to care team? (Yes/No)

   If yes, please describe

4. Do your participants complete both clinical care and research consent procedures? Tell us how that works. Do you encounter participant confusion on what activities constitute research vs. clinical care?

5. Where does study consent take place – is it separated physically or on a different day from delivery of clinical care?

6. What is the scope of genetic/genomic data you are returning? Check all that apply or tell us what categories you are using:

   a. Findings specific to the indication for genetic/genomic analysis

   b. Actionable secondary or incidental findings (ACMG list only, ACMG plus, or a different list)

   c. Pharmacogenetic findings

   d. Carrier status

   e. Non-actionable secondary or incidental findings

   f. Tumor analysis

   g. VUS
      If VUS are returned, do you present these as research findings, clinical findings, both, or neither?

   h. Other (specify)

7. Do you enable participants to decide the scope of results and secondary or incidental findings to be returned to them? Please describe participant options for return.

8. Where are results, including secondary or incidental findings that are shared with the participant, placed?

    a. All in medical record

    b. Some in medical record, some in research records

    c. All in research records

    d. It depends on participant preferences

    e. Other (please describe)

    If any results and incidental or secondary findings are not placed in medical record, where are they stored instead? Which results and findings are recorded outside the medical record?

9. How are research results provided and by whom?

    a. Offered to participants by treating clinicians or research personnel?

    b. Directly to treating clinicians?

    c. Offered to someone else? If so, who?

10. Are the genetic/genomic results in your study generated by a research lab, a clinical lab, a lab that performs both functions, or is it unclear?

11. Is the laboratory CLIA-certified?

    If not, is confirmation in a CLIA-certified lab performed on any results prior to return?

12. What ethics oversight is in place for your study? Indicate all that apply:

    a. IRB

    b. DSMB

    c. Return of Results Committee, Incidental Findings Committee, or similar

    d. Informed Cohort Oversight Board (ICOB)

    e. Community Advisory Board or similar mechanism

    f. Clinical oversight mechanism(s) (e.g., clinical ethics committee, M&M conference, other)

    g. Other

13. Have you obtained a certificate of confidentiality for your study?

14. Have any legal issues been considered and discussed in the design or implementation of your study? Indicate all that apply and describe:

    a. Potential for malpractice claims

    b. Laboratory regulatory compliance

    c. HIPAA or other privacy rules

    d. FDA issues

    e. Other (please describe)

15. How do you distinguish what procedures (if any) related to your study should be billed to insurers?

    Have insurers refused payment? On what grounds?

16. Do you offer testing to family members in your study?

If yes, please describe and indicate when it is a research versus a clinical procedure?

GENERAL IMPRESSIONS ABOUT THE CLINICAL-RESEARCH INTERFACE

17. Are the research and clinical care activities that are part of your CSER project clearly distinguished?

    a. Were you instructed by the IRB to keep them separate? If so, separated in what way?

    b. Can you describe instances in which it was not clear whether research rules or clinical rules applied? How did your team resolve this issue?

    c. How did you and your team approach the mixture of research and clinical functions? What challenges has your team faced in dealing with this?

18. From your standpoint, what are the main differences between research and clinical care in CSER U-award projects? Do you consider these CSER projects to be primarily research, clinical care, or both?

19. Based on your experience, what issues are most important in considering the clinical-research interface? What are the main problems that need to be resolved?

20. How can study designs most effectively negotiate the interface?

21. Are there specific ethical, legal or regulatory issues that merit additional attention? What additional guidance (if any) is needed?

22. Are there any last thoughts you would like to share?

Thank you!