National Center for Biotechnology Information
Standard Operating Procedure for
Resolution of Complaints about Information Submitted to the Genetic Testing Registry

Purpose

This standard operating procedure (SOP) outlines the steps and activities in place to resolve complaints received by the National Institutes of Health (NIH) National Center for Biotechnology Information (NCBI) about laboratory or genetic test information submitted to the Genetic Testing Registry (GTR). It is designed to facilitate consistency in addressing and resolving complaints as well as documenting actions and outcomes.

Submission of Complaints

The GTR enables users to submit complaints, such as breaches of the GTR Code of Conduct,[1] through the "Contact GTR" link on the GTR homepage.[2] This link brings the user to a feedback form,[3] which includes options to "report information that appears to be inaccurate or misleading" and to submit "other comments or questions on the content of the registry."

Procedures

NCBI GTR Staff

1. Feedback forms will be automatically transmitted to NCBI GTR staff,[4] and an automated reply will notify the sender that the form was received.
2. GTR staff will enter all complaints in a database, indexed by the test accession number, for tracking to ensure prompt follow up and resolution.
3. As possible and appropriate, GTR staff will evaluate and address complaints directly (e.g., correcting typographical errors or incorrect URLs).
4. As needed, GTR staff may consult with appropriate experts within or outside NIH[5] for assistance in evaluating complaints.
5. Complaints related to noncompliance with regulatory matters or oversight processes under the jurisdiction of other offices or agencies (e.g., CLIA compliance, FDA regulations, fraud, and scientific misconduct) will be referred to the appropriate office or agency.
6. For complaints related to the GTR Code of Conduct, the GTR staff will inform the content submitter about the complaint and seek a timely resolution of the matter (e.g., a satisfactory explanation about why the complaint is without foundation or an agreement that the submitter's GTR record will be corrected).
7. As appropriate, GTR staff will report the outcome to the complainant.
8. If the complainant is unsatisfied with the outcome, GTR staff will re-evaluate the complaint, and as needed, re-engage with the submitter of the reported content to attempt resolution.

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[1] Code of Conduct for submitters to the Genetic Testing Registry: http://www.ncbi.nlm.nih.gov/gtr/docs/code/.
[2] Genetic Testing Registry homepage: http://www.ncbi.nlm.nih.gov/gtr/.
[3] NCBI Feedback for the Genetic Testing Registry: http://www.ncbi.nlm.nih.gov/projects/gtr_feedback/feedback.cgi.
[4] NCBI GTR Staff refers to staff with laboratory and/or clinical genetics experience.
[5] Consultation outside NIH will not involve consensus advice, and the identities of the complainant and GTR submitter will be kept confidential.

9. If a GTR Code of Conduct complaint cannot be resolved to the satisfaction of the complainant and the content submitter, the GTR staff will notify the GTR Director, who will seek advice from the NIH Clinical Advisors to the GTR, an advisory committee consisting of NIH federal employees with professional expertise in genetic testing and disease.[6]

NIH Clinical Advisors to the GTR

10. The GTR Director will provide information about any unresolved complaint and actions taken by the NCBI GTR staff to the NIH Clinical Advisors using the form *Referral of Complaint to the NIH Clinical Advisors to the Genetic Testing Registry* (see Appendix A).
11. The NIH Clinical Advisors will meet by conference call, in-person meeting, and/or web meeting to discuss the complaint.
12. As needed, the NIH Clinical Advisors may consult with appropriate experts within and/or outside NIH.5
13. The NIH Clinical Advisors will recommend a course of action to resolve the complaint (e.g., removal of a test record from the GTR if inaccurate information is not corrected), which is documented on the form *Referral of Complaint to the NIH Clinical Advisors to the Genetic Testing Registry*.
14. The GTR Director will use the recommended course of action as a guide to re-attempt resolution. If the complainant or submitter of the information in question is unsatisfied with the outcome, he/she may appeal the decision to the NIH Deputy Director for Science, Outreach, and Policy (DDSOP) within 30 days through a letter explaining why the decision should be reversed.

Office of the Director

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15. The GTR Director will provide further information to the DDSOP about the appeal, actions taken by the GTR staff, and guidance from the NIH Clinical Advisors using the form *Referral of Complaint to the NIH Deputy Director for Science, Outreach, and Policy* (see Appendix B).
16. As needed, the DDSOP consults with the GTR Director, appellant, appellee, and appropriate experts to reach a decision.
17. The DDSOP's decision is communicated in writing to the GTR Director, appellant, and appellee, and it is considered final. In some circumstances, it may be made public as well.

Date of SOP Implementation

The SOP for the resolution of complaints about information submitted to the GTR is effective as of November 13, 2012. The SOP will be reviewed one year after implementation and revised, if necessary, based on experience resolving complaints.

Point of Contact

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[6] NIH Clinical Advisors to the Genetic Testing Registry:
http://oba.od.nih.gov/oba/gtr/Roster_NIH_Clinical_Advisors_to_GTR_1-5-12.pdf

APPENDIX A

Referral of Complaint to the NIH Clinical Advisors to the Genetic Testing Registry

1. Date of Genetic Testing Registry (GTR) complaint:
2. GTR record(s) named in complaint (accession and version numbers):
3. Nature of the complaint:
4. Actions taken by NCBI GTR staff (list by date):
5. Summary of the unresolved issue(s):
6. Date complaint was referred to the NIH Clinical Advisors:
7. Course of action recommended by the NIH Clinical Advisors:
8. Date of recommended action(s):

APPENDIX B

Referral of Complaint to the NIH Deputy Director for Science, Outreach, and Policy

1. Date of Genetic Testing Registry (GTR) complaint:
2. GTR record(s) named in the complaint (accession and version numbers):
3. Nature of the complaint:
4. Actions taken by NCBI GTR staff (list by date):
5. Summary of the unresolved issues(s):
6. Date complaint was referred to the NIH Clinical Advisors:
7. Course of action recommended by the NIH Clinical Advisors:
8. Date of NIH Clinical Advisors recommended action(s):
9. Follow-up steps taken by NCBI GTR staff (list by date):
10. Summary of the unresolved issue(s):
11. Date complaint is referred to the NIH Deputy Director:
12. Additional comments: