Part I. How the VHL Alliance will advertise external clinical, behavioral and social science research opportunities:

The VHL Alliance is a conduit for information about opportunities to participate in VHL-related research.

The website will provide external electronic links for reviewed studies, through which users can contact investigators directly to secure additional information. Additionally, the VHL Alliance will utilize its social media channels to disseminate research opportunities.

At cost to the requesting party (postage, paper, envelopes, printing costs, and labor), the VHL Alliance will send registered users a letter that provides a summary of the research opportunity and contact information for the investigators or the VHL Alliance reach out to potential participants by phone.

The VHL Alliance will vet all requests for advertisement of research opportunities as follows.

1. Investigators will provide the VHL Alliance with:
   a. A 2-4 page description of the purpose and design of the planned research that includes clear language about what is being requested of the participants, and includes information about inclusion/exclusion criteria
   b. Proof an Institutional Review Board has assessed the research design for compliance with ethical and safety standards
   c. One or two paragraphs written for a lay audience that are suitable for inclusion on the website or in a letter, contact information for investigators (addresses, email, and relevant telephone numbers), and, when possible, a url that leads to investigators
   d. A CV or resume, stating scientific experience and qualifications to conduct such research.
   e. A selection of requested outreach services: email (free), website (free), social media (free), paper-based outreach (at cost), or telephone (at cost)

2. Within 14 days of receiving a request, the VHL Alliance will circulate the research description and proof of IRB compliance to at least two representatives of the VHL Alliance Research Council. The two representatives will be asked to review the research design for quality and safety, and whether that research could likely be beneficial to individuals served by the VHL Alliance. Finally, they will be asked to give their recommendation on whether to facilitate the request as submitted: Yes or No.

3. The selected members of the Research Council shall have 30 days to give their assessment of the quality, safety and potential benefit of the proposed study, and to develop a facilitation recommendation.
Upon receiving the assessment from the Research Council representatives, the VHL Alliance will write or approve/sign a decision letter within 30 days announcing that the VHL Alliance will support the investigation as submitted or explaining why it will not. This letter will be archived.

The VHL Alliance may request that their decision be postponed up to 30 days until a full vote of the Research Council can be held. In the case that no vote is held in this timeframe, or in the case that the vote of the Research Council is equally divided, the Chair of the Research Council will make the final determination.

4. After approval, the VHL Alliance staff will begin fulfillment within 14 days, and fulfill advertisement on all approved channels within 90 days.

Exclusions:

Only with the approval of the VHL Alliance board will market research be advertised.

The VHL Alliance will not directly solicit the participation of minors on the website, by email or by post. Communications pertaining to pediatric research or underage participants will not directly be marketed to minors, to the extent possible. Some minors may see information on general community communications, but no recruitment efforts will directly target minors. Parental consent will be a prerequisite for enrollment in all vetted studies.

Part II. Researchers may request data from MyVHL: Patient Natural History Study. The VHL Alliance will vet all requests for data as follows.

MyVHL aims to share detailed medical and other information with VHL researchers while protecting patient privacy. Only de-identified data will be provided.

The VHL Alliance reserves the right to charge for the cost of the process for fulfilling the specified request. This includes consideration of staff time invested.

PART II(A). SUMMARY DATA: PRE-IRB DATA REQUESTS

Some researchers may want to avail themselves of registry data to inform the design of future VHL studies, to assess the feasibility of potential future studies, or to strengthen their applications for funding to further examine pressing VHL research questions.

Prior to IRB-approval, researchers are eligible to request summary data (aggregate data)

1. To initiate a request, the interested researcher will submit:
   a. A 2-4 paragraph description of the purpose and design of the planned future research project that includes clear description of how the requested summary statistics will support project advancement
   b. Proof of Human Subjects Research training. (optional)
   c. A CV or resume, stating scientific experience and qualifications to conduct such research
HOW TO APPLY FOR USE OF DE-IDENTIFIED MYVHL DATA
APPLICATIONS TO BE SUBMITTED TO RESEARCH@VHL.ORG

d. A completed form of the summary data requested: the answers to which questions, from which participants

Within 14 days of receiving a request, the VHL Alliance will circulate the research description and proof of IRB compliance to at least two representatives of the VHL Alliance Research Council. The two representatives will be asked to review the research design for quality and safety, and whether that research could likely be beneficial to individuals served by the VHL Alliance. Finally, they will be asked to give their recommendation on whether to facilitate the request as submitted.

2. The selected members of the Research Council shall have 30 days to give their assessment of the quality, safety and potential benefit of the proposed study, and to develop a facilitation recommendation.

Upon receiving the assessment from the Research Council representatives, the VHL Alliance will write or approve/sign a decision letter within 30 days announcing that the VHL Alliance will support the investigation as submitted or explaining why it will not. This letter will be archived.

The VHL Alliance may request that their decision be postponed up to 30 days until a full vote of the Research Council can be held. In the case that no vote is held in this timeframe, or in the case that the vote of the Research Council is equally divided, the Chair of the Research Council will make the final determination.

4. After approval, the VHL Alliance staff will begin fulfillment within 14 days, and fulfill advertisement on all approved channels within 90 days.

PART II(B). PATIENT-LEVEL DATA: DATA REQUESTS FOR PATIENT-LEVEL DE-IDENTIFIED STUDIES

1. To initiate a request, the interested researcher will submit:
   a. A 2-4 page description of the purpose and design of the planned research that includes clear language of aims and hypotheses of the proposed research, where the research will be performed, how the research will be funded, and information about inclusion/exclusion criteria
   b. Proof an Institutional Review Board has assessed the research design for compliance with ethical and safety standards for patient-level, identifiable data
   c. Proof of Human Subjects Research training for investigators requesting patient-level de-identified data. Although the Foundation does not require an IRB exemption letter from the investigator's IRB for patient-level de-identified data requests, it is the sole responsibility of the investigator to adhere to the rules and regulations set forth by their IRB and/or institution if applicable
   d. 1-2 paragraphs about the goal of the study, written for a lay audience, that is suitable for sharing with the public
   e. A CV or resume, stating scientific experience and qualifications to conduct such research
   f. A completed form of the patient-level data requested: the answers to which questions, from
which participants. If re-identified or identifying information data is requested, the researcher must include a justification of the need for such data to meet their study objectives.
Within 14 days of receiving a request, the VHL Alliance will circulate the research description and proof of IRB compliance to at least two representatives of the VHL Alliance Research Council. The two representatives will be asked to review the research design for quality and safety, and whether that research could likely be beneficial to individuals served by the VHL Alliance. Finally, they will be asked to give their recommendation on whether to facilitate the request as submitted.

2. The selected members of the Research Council shall have 30 days to give their assessment of the quality, safety and potential benefit of the proposed study, and to develop a facilitation recommendation.

Upon receiving the assessment from the Research Council representatives, the VHL Alliance will write or approve/sign a decision letter within 30 days announcing that the VHL Alliance will support the investigation as submitted or explaining why it will not. This letter will be archived.

The VHL Alliance may request that their decision be postponed up to 30 days until a full vote of the Research Council can be held. In the case that no vote is held in this timeframe, or in the case that the vote of the Research Council is equally divided, the Chair of the Research Council will make the final determination.

3. After receiving the returned, signed agreement, the VHL Alliance staff will fulfill said request within 90 days.

Part III. Researchers may request inclusion of a new question or set of questions in MyVHL: Patient Natural History Study.

The VHL Alliance reserves the right to charge for the cost of the process for fulfilling the specified request. This includes consideration of staff time invested.

1. To initiate a request, the interested researcher will submit:
   a. The proposed question or set of questions
   b. A 2-4 paragraphs description of the value that the questions would add to MyVHL dataset, including examples of the research questions it would allow researchers to explore
   c. A description of the history of the question(s), including any validation efforts, or known use in other VHL studies. In the case of established questionnaires, a link to the website of the questionnaire creator will suffice

2. Within 14 days of receiving a request, the VHL Alliance will circulate the request to the VHL Alliance Research Council. The Chair, in combination with staff, will schedule discussion of that request (e.g. whether to discuss the request immediately, or at the next scheduled discussion of the registry data model), and share that decision with the Research Council. The meeting will be no more than 1 year after the request. The requesting research will be notified of the anticipated schedule.
3. The members of the Research Council shall give their assessment of whether to include the new question or questions at the meeting designated by the Chair, including a decision of the date to implement data model changes (if applicable).

4. Following the decision of the Chair (developed in consideration of the advisement of the Research Council) will write or approve/sign a decision letter to the requesting researcher within 14 days announcing that the VHL Alliance will support the data model change request as submitted or explaining why it will not. This letter will be archived.