Yale University

Human Investigation Committee
Human Subjects Committee
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APPROVAL OF SUBMISSION VIA EXPEDITED REVIEW

April 27, 2018

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Dear Matthew Grant:

On 4/27/2018, the Yale Human Investigation Committee reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Case series of Bartonella henselae as a cause of fever of unknown origin in solid organ transplant recipients.
Investigator:	Matthew Grant
IRB Protocol ID:	2000023169
Submission ID:	2000023169
Documents:	• Bartonella Medical Record Protocol version 2.pdf, Category: IRB Protocol;

The Yale Human Investigation Committee approved this submission following an expedited review. This approval is valid from 4/27/2018 to 4/26/2020 inclusive.

Review Comments:

This approval is for medical record review only. This approval does not authorize patient contact.

The Principal Investigator has attested that each of the qualifying criteria for an extended approval period of two years has been met, and that future notification of any changes to the following criteria will be made to the HIC/HSC, and confirmed by the HIC/HSC, prior to enacting such changes.

The research study does not include any of the following:

• Any funding, including federal training and program project grants and federal no-cost extensions

• Subawards issued to Yale where the prime award is federal

• FDA regulated components

• Sponsor or other contractual restrictions

• Clinical interventions (including clinical behavioral interventions) that are greater than minimal risk

• Prisoners as subjects

• Receipt of an NIH-issued Certificate of Confidentiality to protect identifiable research data.

Please be advised that Yale-New Haven Hospital and Yale Medical Group have implemented a new reporting request process. Requests for medical records should be made through JDAT as described at http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx.

YNHH and Yale University consider it a violation of patient privacy for research personnel to review medical records of patients who have opted out of research use of their records. All record review requests should therefore be through JDAT.

The IRB finds that informed consent can be waived for this study per federal regulation 45 CFR 46.116(d). This part of the regulations states that 1) this research involves no more than minimal risk to the subjects, 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, 3) the research could not practicably be carried out without the waiver and 4) whenever appropriate the subjects will be provided with additional pertinent information after participation.

A HIPAA waiver has been approved via expedited review for access to and use of PHI from medical records as described in the approved medical record review protocol without obtaining written approval ("authorization") from the subject for the use of the data. This waiver does not authorize subject contact.

The IRB finds that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and (3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

The IRB also finds that the research could not practicably be conducted without the waiver or alteration; and the research could not practicably be conducted without access to and use or the protected health information.

HIPAA regulations require that accounting logs be maintained when researchers access patient records under a waiver of authorization including those approved for recruitment purposes. You are thereby reminded of your obligation to create the log. For further information on maintaining logs and on the accounting of disclosures, please see hipaa.yale.edu.

By 2/25/2020, you are to submit documentation for a continuing review. You can request a continuing review by navigating to the active study and clicking Create Modification / CR. Alternatively, you can close the study when the study procedures and the data analysis of identifiable data are fully complete. You can submit a closure request by navigating to the active study and clicking Create Modification /CR.

If you wish to change any aspect of this study, such as the study procedures or processes, the informed consent document(s), recruitment activities, or wish to add or remove investigators or study personnel, you must submit a modification to the study. Any changes must be approved by the IRB prior to implementation.

Serious, unanticipated, and related adverse events, and unanticipated problems involving risk to subjects or others must be reported generally within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events).

In conducting this study, you should refer to and follow the Investigator Manual (HRP-103), which can be found in the IRB Library within the IRB system.

Please keep this letter with your copy of the approved protocol documents.

Sincerely,

Human Investigation Committee