

## DEMYSTIFYING THE HHS WAIVER PROCESS

by Suzanne Seltzer\*

The “J” exchange visitor program permits researchers, scholars, professors, medical trainees, and others to come to the United States to participate in a sponsored program. According to the U.S. Department of State, the J-1 program is designed to promote the interchange of persons, knowledge, and skills in the fields of education, arts, and sciences.<sup>1</sup> Since the purpose is the exchange of information, knowledge, and skills, many exchange visitors are required to return to their home country at the completion of their program, to share their newly acquired information, knowledge, or skills.<sup>2</sup> Yet in many instances, those with a two-year home requirement are reluctant to return, and if it can be established that their continuing presence is in the interest of a U.S. government agency, they may not have to.<sup>3</sup>

There is only a handful of U.S. Interested Government Agencies (IGA) that have a formal application process to initiate a waiver recommendation.<sup>4</sup>

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<sup>1</sup> [www.travel.state.gov/visa/tempvisitors\\_types\\_scholars.html](http://www.travel.state.gov/visa/tempvisitors_types_scholars.html).

<sup>2</sup> Immigration and Nationality Act of 1952, Pub. L. No. 82-414, §212(e), 66 Stat. 163 (codified as amended at 8 USC §§1101 et seq.) (INA).

<sup>3</sup> *Id.* Note, this article is limited to waivers through an IGA. Other options for waivers may include: state health agency recommendation, hardship to a U.S. citizen or permanent resident spouse or child, fear of persecution in the home country, or a statement of no objection from the home country.

<sup>4</sup> IGAs do not grant waivers. The authority to grant waivers is made by USCIS. The IGAs have the authority to recommend waivers to the Department of State, which then re-

*continued*

These include, *inter alia*, the National Science Foundation, the Department of Defense, the Department of Energy, and the Department of Health and Human Services.<sup>5</sup> Waivers submitted to these IGAs are given technical review by relevant experts in the field. Therefore, such applications require a sophisticated level of scientific and technical information demonstrating why the applicant's continued presence in the United States is in the interest of that IGA. As a result, it is often difficult for advocates or institutions, who are not necessarily scientific experts, to advise on these petitions or provide effective guidance and assistance.

The purpose of this article is to evaluate the IGA waiver process via a review of the Department of Health and Human Services (HHS) Exchange Visitor Waiver Review Board's procedure.<sup>6</sup> The specifics of this procedure were provided by the administrator of the Exchange Visitor Waiver Review Board (Board) at HHS.<sup>7</sup> Through this evaluation, it is hoped that much needed insight will be afforded, providing concrete suggestions that can be incorporated into an effective practice.

One of the most important points to keep in mind when both advising on, and preparing, an HHS waiver application is that it is not an O-1 nor an immigrant visa petition. Eligibility for the O-1 or similar types of immigration petitions (*i.e.*, outstanding researcher, na-

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views the application and makes its recommendation to USCIS. Note that the lack of a formal program does not preclude a federal agency from recommending a waiver.

<sup>5</sup> These are not the only IGAs that may recommend a waiver. Any IGA may recommend a waiver of the two year home residency requirement. For example, the Federal Trade Commission and the Department of Commerce have acted as an IGA where it was established that doing so was in the interest of their agency.

<sup>6</sup> 45 CFR Part 50.

<sup>7</sup> As of the time of writing, Joyce Jones was the administrator of the HHS waiver program, and references to “HHS” or “the administrator” were based on her comments.

tional interest waiver, alien of extraordinary ability) do not necessarily translate into a successful HHS waiver. This is because the O-1 visa petition and the HHS waiver application have a completely different set of standards, and are reviewed by very different audiences. Supporting letters from the O-1 petition should not be included with the HHS application, nor should the plethora of supporting documentation used to corroborate the O-1 eligibility criteria. In stark contrast to U.S. Citizenship and Immigration Services (USCIS) adjudications, HHS accepts as true the accomplishments included in the applicant's curriculum vitae (CV). Therefore, separate documentation for each and every point raised is neither necessary, nor sought by HHS in its review of the waiver application. In fact, "less is more" would be a more apt approach.

If "less is more," how does the 'less' become 'more'? Basically, by understanding and focusing on the key issues that HHS relies on in making a waiver recommendation. In order to facilitate this understanding, HHS has issued a supplemental information sheet,<sup>8</sup> outlining the principal points that should be addressed in the application. In submitting a waiver request application, each of these points should be enumerated and addressed by the employer/institution as they are listed on the supplemental information sheet, and signed by the Principal Program Officer.<sup>9</sup> The following guidance in addressing these points is based on suggestions made by HHS regarding what specific information should be provided:

1. *Complete Description of Program or Activity Including How It Serves the National Interest*—This should be a concise, *scientific* description of the research program in which the exchange visitor is involved. The emphasis is on *science* and *succinct*. HHS does not need a detailed description of the institution itself, or platitudes regarding the institution's standing in the field. Moreover, it is not necessary to assert how important this research is to the National Institutes of Health (NIH), as the application is adjudicated by NIH/HHS, and it will make its own determination if it is in fact important to the relevant agency. However, if the program is sup-

ported by a NIH grant, *the grant name and number should be included.*

2. *Exchange Visitor's Essentiality to the Program and Unique Capabilities*—The section on essentiality is one of the most misunderstood of HHS' criteria. This section should not be a detailed description of the applicant's background and accomplishments, which made them "essential" to the program. Rather, what HHS is looking for in this section is the applicant's day-to-day role in the program, his or her specific job duties relevant to the program itself. HHS is not interested in applicant's teaching or training responsibilities, but only in the applicant's scientific role in the program. In discussing applicant's job duties, it is helpful to include any unique or rare technical expertise, or combination of disciplines essential to the work. If such expertise is essential to the research, even a recent graduate or post-doctoral fellow may be an appropriate waiver candidate. It is also important to include information on grant funding awarded to applicant either individually or as the principal investigator (PI) of a project.

3. *Information Regarding Current Personnel*—The application should address this point to reinforce the applicant's essentiality to the program, and describe how exactly the applicant fits into the program. HHS is interested in the skill sets of the others involved in the program to the extent that they rely on applicant's skills for their own work, and to understand why such other personnel would not be able to step in and pick up applicant's responsibilities, if the applicant were no longer available. HHS is not interested in the distinguished reputations of these people, but rather how their skills sets interact with, or complement, that of the applicant for purposes of the research.

4. *Recruitment Efforts*—Again, in order to ensure that the applicant is essential to the program, HHS wants evidence that at least one ad was placed in a national journal in search of a replacement with the appropriate skill set. The salary, or a statement that "salary will be commensurate with experience," should be included in the ad. The recruitment summary should be kept brief and simple: (a) where and when the ad was placed; and (b) any responses from qualified applicants.

5. *Future of Program if Waiver not Granted*—If, in fact, the applicant is essential to the program, there

<sup>8</sup> Available at [www.globalhealth.gov/supplementA.shtml](http://www.globalhealth.gov/supplementA.shtml).

<sup>9</sup> HHS will only consider waiver applications supported by an institutional sponsor. Individuals may not self-petition for the HHS waiver.

are going to be some repercussions if the waiver is not granted and the applicant is required to fulfill the two-year home residency requirement. One way to document such consequences is to note delays in the research prior to applicant joining program, or anticipated delays if applicant were no longer available to contribute. Another critical element would be any program funding belonging to applicant that would be lost if applicant had to leave, potential funding that applicant is currently precluded from obtaining because of immigration status, or program funding dependent on applicant's skill, regardless of whether he or she is listed in the actual grant.

6. *Long Range Plans for Exchange Visitor*—In three sentences or less, describe the institution's intentions for the applicant. For example, for what promotions may the applicant be considered, either tenure-track or advanced research track.

As opposed to the first six points on the supplemental sheet, the seventh point is not one that needs to be addressed by the employer support letter. The seventh point requests "*Information Concerning the Exchange Visitor's Qualifications, Including Evidence of Special Accomplishments and External Letters of Recommendation.*" These external support letters should come from outside the sponsoring institution. The text of these letters should address the applicant's history of excellence in the context of the research program, as well as other accomplishments for which the applicant has received recognition. When advising on the number and type of external support letters, do not include letters that basically reiterate the same point, and do not use the letters from the O-1—particularly if they are still addressed to "USCIS." Since this is a peer review process, letters should be written from one scientist to another, and should not include platitudes or superlatives in their description. It is important to use letters from recognized experts in the relevant field, but HHS' supplemental information sheet specifically requests that **only the applicant's CV** be included. One would hope that HHS is already familiar with the letter writer's reputation and accomplishments. If HHS is not familiar with the letter writer's reputation, the letter itself may not be given the same level of consideration as a letter from a more established expert.

While the institutional support letter and the external letters of recommendation are critical to the application, there are other documents that must be

included as well. Similar to any USCIS submission, the appropriate form with the appropriate authorized signatures must also be included. For the HHS waiver, it is HHS Form 426.<sup>10</sup> HHS Form 426 requires two signatures: (1) the principal program officer, defined as the individual who can answer substantive questions regarding the research; and (2) administrative officer authorized to sign on behalf of the institution as a whole, not just the specific department where the research is being conducted. The waiver review board at HHS maintains a list of the appropriate individuals at each institution authorized to sign, which is usually someone in the office of international scholars or the immigration office at the institution. HHS is very concerned that the institution as a whole, and not just the applicant's department, supports the waiver application and, therefore, ensuring the appropriate administrative signature on the form is absolutely critical to the process. *If no one is designated, the institution's general counsel should contact the Waiver Review Board to appoint someone, and submit such authorization to HHS in writing.* If outside counsel is representing the institution in the submission, a G-28 should also be included, signed by the administrative officer.

The forms, support letters, and other documentation should be compiled and submitted in the following suggested order:<sup>11</sup>

- Cover Letter
- G-28
- HHS Application Form 426
- Applicant's CV
- Applicant's immigration documents (IAP-66s, DS-2019s, I-94, I-797s)
- Applicant's publications (limited to a selection of the most recent full manuscripts);
- Employer's support letter
- Recruitment efforts (copy of ad)
- External letters of support

In noting what should be included with the application, also note what should not be included, as in-

<sup>10</sup> [www.globalhealth.gov/exchangevisitor.shtml](http://www.globalhealth.gov/exchangevisitor.shtml).

<sup>11</sup> Note that the Department of State (DOS) Waiver Review case number does not need to be included at the time of filing, but will need to be submitted prior to HHS issuing a favorable recommendation to DOS.

cluding it would only impede the waiver review process. This includes the CV of anyone other than the applicant, background information about the sponsoring institution or the importance of the research program (HHS will make its own determination of the importance of the program), full copies of grants (simply provide the grant name and number), applicant's honors and awards, applicant's older publications (HHS suggests submitting only those from the last two years or those that are considered "important"—but generally no more than 10 publications), citations to his or her work, requests for reprints, *or* anything else included in applicant's CV. As noted above, HHS will review the applicant's CV and trust that it is accurate. Moreover, the cover letter from counsel should simply be a list of what is included, not a summary of the evidence nor a treatise on why a favorable recommendation of the waiver is warranted.

Applications received by HHS are first administratively reviewed by the Waiver Review Board's Executive Secretary to ensure that the requisite information is included. If the application is not properly prepared, it may be literally taken apart, as it must fit within a folder that will then travel to each of the individuals involved in the review process.

There are a number of different people within HHS that are involved in the review process. These individuals are housed in different offices in different parts of the city. Therefore, the file literally travels from one office to another. Because of the limited room available in the file, any documentation considered extraneous may be discarded. Moreover, since the file travels, once the formal review process has begun, no additional information should be added to the file. The need for the file to travel is one of the causes of the delays experienced in the adjudication of the waiver. Another cause of delay is that nearly everyone involved in the review process is a full-time scientist, and their role in the review process is a service they perform on a volunteer basis, in addition to their already busy schedules.

If the application is missing basic documentation necessary for Board review (*e.g.*, institutional support letter, HHS form, appropriate signatures), the administrative official of the sponsoring institution or the attorney of record will be contacted. Note that applications missing basic documentation may incur lengthier processing times. Once it is determined that

the application is complete, a "receipt" letter is sent either to the institution or to the attorney of record.<sup>12</sup> It is at that point that the scientific review commences. However, because the application must first be administratively reviewed and prepared for the scientific review, it may be 3-6 months following submission before a formal "receipt" is issued.

The first part of the scientific review is a "Technical Review." The technical review is not done by members of the Board, rather the technical review is done by experts within the appropriate HHS institute most interested in the research program. If there is an NIH grant supporting the research, the technical review will be done by the grant source. The technical review does not evaluate the application to ensure compliance with the waiver requirements, but rather to render an opinion as to the scientific value of the program, and of the applicant's accomplishments/publications. However, the technical reviewers do supply an opinion as to whether the waiver should be recommended. Since this opinion is generally based solely on the scientific merit of the program, and not on the HHS waiver policy, it is used only as a guide for the Board.

After the technical review is completed, the reviewers' comments are returned with the file to the Waiver Review Board's Executive Secretary, who then selects two members of the Board (out of a list of five) to review the application. The list of five Board members includes scientists emeritus who are not necessarily experts in the relevant field.

The role of the Board is to apply the policy and goals of the HHS waiver program as articulated in its regulations. This basically requires weighing the technical evidence against the regulatory criteria; the importance of the program itself and the absolute essentiality of the applicant to the continuation of the program, in contrast to policy considerations of enforcing the two year home residency requirement. The Board considers factors such as the applicant's salary, publication record, technical or multi-disciplinary expertise, and potential (*i.e.*, if applicant is on track to become a stand-alone researcher). More and more, the Board is recognizing the importance of clinical research, particularly as bench and clinical research are increasingly overlapping.

In considering applications from clinical researchers, the Board looks closely at the percentage of time spent on research versus purely clinical care, as well as the applicant's publication record. In any case, it is important to note that NIH/HHS grants are not decisive; research programs funded by other agencies, industry, or even internally by the institution may be eligible for a waiver. The key factor is whether HHS believes this specific research program is important and what the applicant's role in the program is.

The Board does not actually meet. The two Board members provide written comments on the merits of the application. If they agree, their decision is followed. If they disagree, the Executive Secretary may act as the tie breaker. In this regard, she may request additional information, check the specific grant to verify the applicant's time commitment, check if the applicant's work is discussed in the grant's annual report, or decide that a favorable recommendation is not warranted. If an application is not recommended for a waiver, the sponsoring institution is sent a letter informing them simply of that fact. If the institution wants more detailed information regarding the deficiencies of the application, it must request it in writing. HHS will give institutions one opportunity to cure any deficiencies.

According to HHS, the Board makes favorable recommendations in about 60 percent of the approximately 200 applications they receive each year. While applications that follow the suggestions provided by this article are not guaranteed a favorable recommendation, they may at least enjoy a facilitated adjudications process. More importantly, these suggestions will hopefully assist in advising clients not only as to the preparation of the application, but also in providing a more informed opinion as to the likelihood of success of the waiver application.