



1019 39th Ave SE / Suite 120  
Puyallup, WA 98374  
855-818-2289  
www.wcgirb.com

Date: 23 August 2021  
To: Valued Clients  
From: Dawn Pope, CIP; Senior VP, Client Experience  
Re: WCG IRB Translations Process Updates

WCG IRB is continually working to ensure that our processes are ones that deliver IRB reviewed materials to you as accurately and efficiently as possible.

We are sending this communication to inform you of a few procedural changes that we have made to our Translations process.

If you **are supplying your own translations to WCG IRB** for review and approval, effective immediately, the following will apply your submissions:

1. Consent forms must be submitted in Word format to the IRB:
  - Submissions made in PDF or other formats will not be accepted.
2. When you receive approved versions of revised documents, and if non-English speaking participants are active on your trial, it is WCG IRB's expectation that you will submit updated translated versions of those materials within 30 days for IRB review/approval accompanied by an updated Certificate of Translation (CoT).
3. Translated materials that are submitted prior to approval of the corresponding English material(s) will no longer be accepted.
  - The Board often requires changes to the English material(s) during review that will then need to be applied to the submitted translation(s).
4. Translated Consent Forms, Subject Materials, and/or Advertisements must be submitted with appropriate identifiers on the document or accompanying the documents so that the translated items can be easily matched to their already-approved English counterparts.
  - Submissions made without the appropriate identifiers will not be accepted, as WCG IRB utilizes this information for version controlling purposes.

Provided below are several methods for submitting your translations to ensure WCG IRB staff can accurately match up your submitted translated document to the corresponding WCG IRB English approved version in a speedy, accurate fashion –

**Option 1:** Fill out the WCG IRB online or Adobe form with the required information (WCG IRB approved English document title and submitted translated document title)

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\*Are you submitting documents translated by an external vendor for IRB approval?

Yes  No

If yes, for each translated document, attach:

- Translated document (*Word documents are required for consent form submissions*)
- Certificate of Translation (COTs) (*Must include the document title as it appears on the IRB Certificate of Action, Sponsor Protocol #, Sponsor name, source and target language are listed, documentation of consent form versioning (i.e. English IRB approval date, or IRB issued legend code), and that the translator is fluent both languages/otherwise able to translate, and that the document is an accurate representation of the English.*)

For each document submitted, provide the following information:

Document file name:

Spanish - Greenphire ClinCard Cardholder Agreement - Visa-US (v1.0Apr2020) with TC.pdf

Document title as it appears on the IRB Certificate of Action:

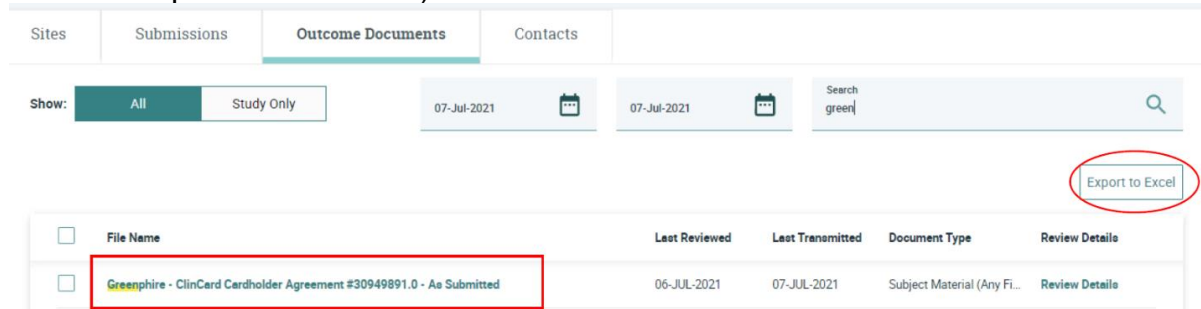
Greenphire - ClinCard Cardholder Agreement #30949891.0

**Option 2:** Copy the English WCG IRB approved document titles from the Connexus portal, IRBNet portal, or the Certificate of Action into a new document with two columns listing the WCG IRB English approved document title and the corresponded submitted translated document:

**For example:**

Submitted translated document title:	WCG IRB English document title
Spanish - Greenphire ClinCard Cardholder Agreement - Visa-US (v1.0Apr2020) with TC.pdf	Greenphire - ClinCard Cardholder Agreement #30949891.0

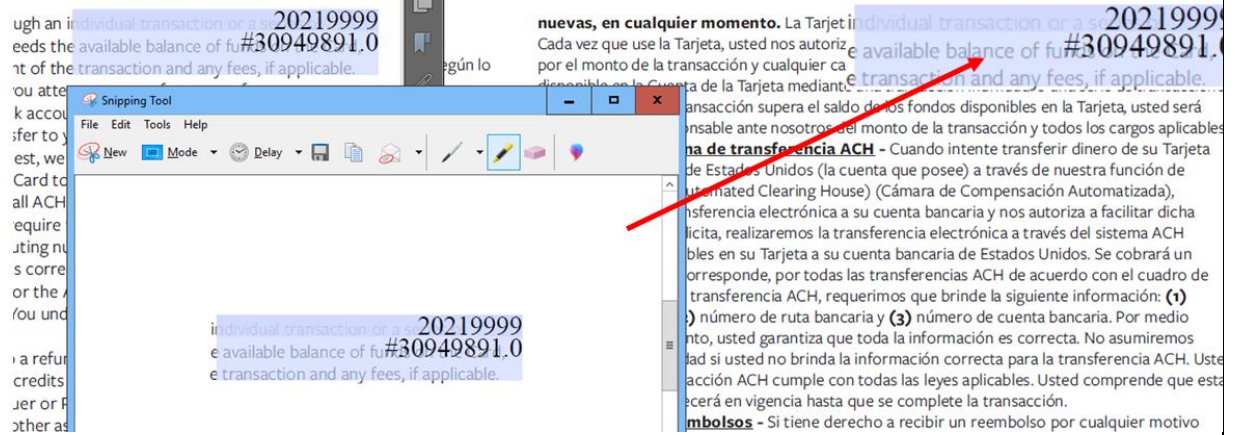
To obtain the exact WCG IRB English document title, copy and paste titles from the document portal your organization relies on (Connexus, IRBNet). (Connexus users can also export titles to excel)



The screenshot shows the 'Outcome Documents' tab in the Connexus portal. It displays a table with columns for 'File Name', 'Last Reviewed', 'Last Transmitted', 'Document Type', and 'Review Details'. One document is listed: 'Greenphire - ClinCard Cardholder Agreement #30949891.0 - As Submitted'. An 'Export to Excel' button is circled in red in the top right corner of the table area.

**Option 3:** Use a Screen Capture tool (like the Snipping Tool on a Windows PC) to copy our IRB document identifiers (IRB protocol number and IRB document number)

onto your submitted document:



**Option 4:** Incorporate the WCG IRB English document title into the title of the submitted document:



5. Standardized documents in use on your trial:

- WCG IRB does not require that commercially available validated instruments (English or non-English) be submitted to the IRB for review/approval if they are in use on your protocol; but
  - if they are submitted to the IRB to review/approve in English, they will be required to be reviewed/approved by the IRB in any non-English language you wish to utilize for your trial.
    - You would then be required to submit the translated standardized forms to WCG IRB with the same identifiers noted above.
- When you purchase the translated versions of those commercially available validated instruments WCG IRB does not require a CoT (as long as it has not been altered from the original format).

6. How to consent non-English speakers if you have not received approval of a translated consent form from the IRB yet:
  - WCG IRB has adopted a policy regarding use of the short form consent process to enroll participants who do not speak English. Please review the relevant section of our "[Guide for Researchers](#)" on page 31 for the details on the policy.

Last, our Translation Request Form has been revised. To access a copy of this smart form, you can obtain one from Connexus or [on our website](#).