

FWAs are submitted electronically. This is for you to review first.

<http://www.hhs.gov/ohrp/humansubjects/assurance/filasur.htm>

New Filing Update or Renewal for FW A Number: _____

**U. S. Department of Health and Human Services (DHHS)
 Federalwide Assurance (FWA) for the Protection of Human Subjects
 For Domestic (U.S.) Institutions**

1. Institution Filing Assurance

Legal Name	Small business with federal grant (aka SBWFG)
City and State	Anywhere, CA
DHHS Institution Profile File (IPF) code, if known:	none
Federal Entity Identification Number (EIN), if known:	xx-xxxxxxx
If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:	none

2. Institutional Components

List below all components over which **SBWFG** has legal authority that operate under a different name. *(Does SBWFG have any satellite clinics? Any manufacturing plants where employees are subjects? Any school districts? Any sub-corporations? One clue is whether the person signing has the right to sign for the component institution being listed.)*

Also list with an asterisk (*) any alternate names under which the Institution operates. *(*SBWFG aka Small Industries)*

<input type="checkbox"/> There are no other components.			<input type="checkbox"/> There are no other alternate names.		
Or					
Name of component		City		State	
*Alternate names used					
SBWFG Mfg plant		Anytown		CA	

The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request, a brief description and line diagram explaining the interrelationships among the components including:

the Assurance Signatory Official, *(the person making the promises)*

the Institutional Review Board (IRB), (*how our IRB is integrated into your program*)
 IRB support staff, and
 investigators in these various components.

3. Statement of Principles

SBWFG assures *PROMISES* that all of its activities related to human subject research, *regardless of funding source, (BE careful to make sure that your policy says you will apply the checked principles to ALL of your studies. IF not, explain to OHRP.)* will be guided by the ethical principles in the following document(s).

- The Belmont Report**
 Other: (Please attach) ICH? CIOMS? APA?

4. Applicability Be careful of this question...

This is referred to as checking (or unchecking) the box. You do not need to check either box.

- (a) **SBWFG** assures that **ALL** of its activities related to federally-conducted or -supported human subject research will comply with the Terms of Assurance for Protection of Human Subjects for Institutions Within the United States.
 (NOTE: The Terms of Assurance are contained in a separate document on the OHRP website. **READ IT! YOU ARE MAKING PROMISES!!!**)

OR

- (b) *Optional:* **SBWFG** elects to apply the following to all (**ALL!!!**) of its human subject research **regardless of source of support:**
 45 CFR 46 and all of its subparts (A,B,C,D)
B, C, and D relate to vulnerable populations.
 Common Rule (e.g., 45 CFR 46, subpart A only)

5. Designation of Institutional Review Boards (IRBs)

SBWFG designates the following IRB(s) for review of research under this Assurance *This section is for naming the IRB that is considered the institution's IRB.*

NAME of IRB as registered	Registration Number
IRC – Independent Review Consulting	00000762
OTHER IRBS UPON WHICH SBWFG MAY RELY	

NOTE: For occasional reliance, other documents may be used to show agreement between the two institutions or between the institution and an IRB. The agreement may be OHRP's sample IRB Authorization Agreement from their web site, IRC's form or the other institutions form.

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

Name (first, middle, last and Degree)	John J. Smith, CIP, MBA, D.Phil.
Institutional Title	Undersecretary for Research
Institution	SBWFG Small business with SBIR
Address	Xxx Maple
City and State	Anywhere CA
Telephone	xxx-xxx-xxxx
Fax	xxx-xxx-xxxx
e-mail	jjs@smallbusiness.net

7. Signatory Official

This person has signatory authority for all components listed in section 2.

Name (first, middle, last and Degree)	Annie A Smith, MBA, MD
Institutional Title	President
Institution	SBWFG - Small Business Hoping For Money
Address	XXX Maple
City and State	Anywhere CA
Telephone	xxx-xxx-xxxx
Fax	xxx-xxx-xxxx
e-mail	AAS@sbsbir.net

I assert and/or understand that

- I have the legal authority to represent the Institution providing this Assurance and all components listed in section 2.
- I am not the IRB chairperson nor am I on the IRB at all.
- I have completed the Assurance Training Modules on the OHRP website which describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance.
- I recognize that providing all research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.
- The IRB(s) designated above are to provide oversight for all research conducted under this Assurance. These IRB(s) will comply with the **Terms of the Assurance** and possess appropriate knowledge of the local context in which this Institution's research will be conducted.
- I understand that all collaborating institutions engaged in federally-conducted or -supported human subject research must submit their own Assurance.
- All information provided with this Assurance is up to date and accurate.
- I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Acting officially, in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above.

Signature _____

Date: _____

(8) DHHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to DHHS by the above Institution is hereby approved.

Assurance Number: _____

Expiration Date: _____

Signature of DHHS Approving Official: _____

Date: _____